

Exhibit 30

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DIMETHYLFORMAMIDE: PURIFICATION,
TESTS FOR PURITY AND PHYSICAL
PROPERTIES

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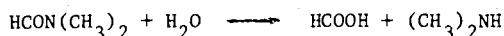
Commission on Electroanalytical Chemistry

DIMETHYLFORMAMIDE: PURIFICATION, TESTS FOR PURITY AND PHYSICAL PROPERTIES[†]

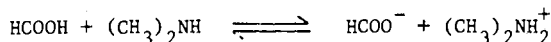
N,N'-Dimethylformamide (DMF) is a good solvent for organic and to a lesser extent inorganic compounds. It is, together with dimethylsulfoxide and acetonitrile, one of the most widely used of the so-called dipolar aprotic solvents. Owing to its fairly high dielectric constant, it is a moderately dissociating solvent for electrolytes. Acid-base reactions as well as thermodynamic properties of electrolyte solutions have been studied by many authors. Contrary to the N-methylamides it is a typically weakly associated solvent, as seen (Ref. 1) from dielectric studies (the Kirkwood g factor is about one at all temperatures).

Owing to its electron-donor character, DMF reacts with many acids. For example, Gutmann's donicity number (Ref. 2) is 27. Its polarographic range is quite large, e.g., 3.5 V at the dropping mercury electrode with 0.1 M Bu₄NC10₄ as supporting electrolyte (Ref. 3). It is therefore widely used as a solvent for electrochemical reactions, especially reductions.

Pure DMF is colorless and, at room temperature, odorless. It is subject to thermal as well as photochemical degradation. In presence of water, DMF is slowly hydrolyzed according to the equation:



Formic acid and dimethylamine are thus predominant impurities in DMF and determine the odor of the impure solvent. They are weakly acidic and weakly basic respectively; therefore, partial ionization does occur:



and results in a buffered solution (pH 11) with an increase in the conductivity of the solution.

Thermal degradation produces dimethylamine and carbon monoxide. Hydrogen (Ref. 4) and hydrogen cyanide (Ref. 5) have been identified among the products of the photochemical degradation of the solvent.

Strongly basic media are difficult to obtain in DMF; there is, to our knowledge, no substance behaving as a strong base in DMF. If autoprotolysis of the medium actually occurs, the anion of the solvent must be very unstable (Ref. 6). It has been claimed (Ref. 7 and 8) that the autoprotolysis constant is smaller than 10⁻²⁵ but no definite value has yet been proposed.

Attention must be paid to the fact that DMF has toxic effects, particularly on the liver and kidneys; the threshold value for air has been fixed (Ref. 9) at 30 mg/m³.

PURIFICATION OF DIMETHYLFORMAMIDE

Good quality DMF is commercially available. As noted by Vaughn (Ref. 10), spectrograde solvent is not always suitable for all purposes. As a consequence of hydrolysis, the residual water content of commercial DMF is frequently low (0.1%). Many procedures have been proposed and used for the purification of the solvent. Four types of successive operation can be distinguished: treatment with a drying agent, neutralization of basic or acidic impurities, careful distillation, and elimination of gaseous impurities.

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1. Preparing water-free solvent. Although the boiling point of water is far from that of DMF it is not possible to obtain a dry solvent by distillation only.

One of the first methods proposed for preliminary drying (Ref. 11) was azeotropic distillation with about 10% by volume of dry benzene; the benzene-water azeotrope is removed by distillation at atmospheric pressure. To prevent decomposition the temperature is maintained below 80°C. Alternatively, molecular sieves can be used. The solvent is kept in contact for periods ranging from 1 to 4 days with 4 Å (Ref. 12-15) or 5 Å (Ref. 16) sieves which are removed and replaced from time to time. Ritchie (Ref. 17) recommends the use of Linde AW-500 molecular sieves in 1/16-inch pellets. Studying drying efficiency, he finds that the water content is less than 18 ppm after 27 hours. Molecular sieves can be dried before use by heating in a quartz tube under a stream of argon at 375°C for 24 h (Ref. 18). Finally, a procedure which uses chromatographic purification through alumina has been described by Moe (Ref. 13) in some detail. "A column approximately 100 cm long and 5 cm wide will contain 1 kg of alumina, sufficient for the purification of about 10 l of DMF". After bubbling of pure nitrogen for several hours the DMF thus obtained is thought to be convenient for polarographic use.

In our opinion these three types of operation can be considered only as a first step in drying the solvent, and mild chemical drying agents must also be used. These range from anhydrous BaO (Ref. 11 and 19) to MgSO₄ (Ref. 20), Na₂CO₃ (Ref. 6 and 20), or CuSO₄ (Ref. 21). Surprisingly good samples of DMF can be obtained using storage of solvent over these chemicals for at least 24 h. It has been recommended that the drying agent be changed at least twice and the container shaken, if not continuously, at least from time to time. It also has been recommended that such an operation is performed in a cold, dark room. As far as Na₂SO₄ or Na₂CO₃ are concerned, the resulting solvents are of about the same quality (Ref. 20). Little or no degradation of the solvent (as estimated through the concentration of dimethylamine) results from such treatment (Ref. 11).

Some of the more common drying agents react with the solvent itself to produce significant amounts of acidic or basic impurities. BaO, cited previously, belongs to this category if it is used at temperatures above 30°C (Ref. 11). Other reagents are potassium hydroxide, calcium hydride (Ref. 5 and 22) and phosphorus pentoxide (Ref. 17, 23 and 24). P₂O₅ is the most frequently used, CaH₂ is probably the most efficient. Prue and Sherrington (Ref. 23) have shaken DMF for three days with P₂O₅, adding each morning about 10 g of fresh reagent. Recently, drying of amides using Vitrid, sodium bis(methoxy-2-ethoxy)aluminumhydride, has been recommended (Ref. 25). In DMF it allows attainment of very basic media (pH 30). However, distillation of the solvent from the mixture obtained has not been attempted and is probably very hazardous. Whatever the method used, it is important to proceed with these operations in a dark room or apparatus to prevent any photochemical degradation.

2. Neutralization. Depending on the drying agent used, it has been recommended that the basic or acidic impurities produced are neutralised, either by shaking with picric acid (Ref. 20) or KOH pellets (Ref. 24). This last treatment is particularly recommended after drying over P₂O₅ which generates formic acid. Such neutralization can be done either before or after a first distillation.

3. Distillation. The drying process can be further carried out during this operation. The DMF is refluxed and distilled from P₂O₅ or CaH₂. However, owing to a degradation process increased by heating, it is preferable first to decant the solvent and transfer it under dry nitrogen, and then to distil it at reduced pressure.

The quality of the final product is greatly affected by the care with which the distillation is carried out. It seems to be important to work under vacuum, with a darkened column, or in a pure nitrogen or argon atmosphere. As a rule, the temperature must be kept under 60°C; heating must be gentle and overheating avoided. Distillation in daylight results in the production of hydrogen cyanide (Ref. 5), particularly in the presence of CaH₂. No traces of HCN are detected if the operations are conducted in the dark.

Types of distillation apparatus currently described in the literature do not seem to be very efficient. It is not surprising to note that the best quality DMF, if conductivity is accepted as a test of purity, has been obtained by Brummer (Ref. 12), who used only molecular sieves as drying agents, but carried out the distillation in a slow current of dry nitrogen at low pressure (2 torr) and an efficient column (1 meter packed with Fenske helices). The use of a long column (60 cm at least) with good packing and reflux is recommended. For example, Tanaka (Ref. 21) distilled DMF which had been dried over anhydrous CuSO₄ at a pressure of 5 torr through an adiabatic fractional distillation column which was 1.3 cm in diameter, 120 cm in length and packed with helipack coils. Dry nitrogen was passed through the apparatus during the distillation; 60% of the distillate was collected. The conductivity was lower than $1 \times 10^{-7} \Omega^{-1} \text{ cm}^{-1}$ (25°C). Boiling temperatures at various pressures are given in Table 1.

TABLE 1. Recommended values for physical constants of DMF at 25°C and 1 atm (except where noted otherwise)

Boiling temperature	T_B	152.3°C (Ref. 47)
		79°C at 61-62 torr (Ref. 37)
		55-56°C at 25-26 torr (Ref. 40)
		34°C at 2-3 torr (Ref. 15)
Melting temperature	T_M	-61°C
Refractive index (Ref. 44)	n_D^{25}	1.42689
Dielectric constant	D	37.0
Surface tension (Ref. 45)	σ	37.1 dyne/cm
Viscosity (Ref. 23)	η	0.00796 poise
Density	ρ	0.9440 g cm ⁻³
Molal volume	V	77.39 cm ³
Heat capacity at constant pressure (Ref. 44)	C_p	37.4 cal/mol
Cubic expansion coefficient	α_p	1.00 x 10 ⁻³ K ⁻¹ *
Adiabatic compressibility coefficient (Ref. 44)	β_S	6.1 x 10 ⁻⁵ atm ⁻¹
Isothermal compressibility coefficient	β_T	6.3 x 10 ⁻⁵ atm ⁻¹ *

* Calculated from data in Ref. (12)

4. Elimination of gaseous impurities. A flow of pure dry nitrogen or argon is passed through the solvent for several hours, in order to eliminate oxygen, carbon monoxide and carbon dioxide. Such a solvent can then be used for polarographic purposes. A more complete deaeration can be achieved using a vacuum line.

5. Conclusions and recommendations. As various authors used different starting materials, it is difficult to compare the efficiency of the various methods of purification. Comparison between different ways of treating the same batch of solvent can be found to our knowledge in only two papers (Ref. 11 and 20). Thomas and Rochow (Ref. 11) always used first azeotropic distillation with benzene and compared subsequent treatment with MgSO₄, BaO, alumina and triphenylchlorosilane, followed in each case by distillation. Comparisons were made in terms of specific conductance and water content. Barium oxide as well as alumina treatment meet rather well these two criteria and do not have any side effects, such as producing dimethylamine or HCN. Juillard (Ref. 20) compared drying with Na₂CO₃, Na₂SO₄ or molecular sieves with azeotropic distillation with benzene and distillation over P₂O₅. As far as conductivity and water content are concerned, the different batches of solvent thus obtained were of about the same quality, except that P₂O₅ has the disadvantage of promoting degradation of the solvent and thus of decreasing the efficiency of the distillation; therefore the use of P₂O₅ is not recommended. As a confirmation it can be noted that authors using P₂O₅ or CaH₂ as drying agents did not obtain purer solvents than those who employed BaO or Na₂CO₃ or even only molecular sieves.

It is therefore recommended that use is made first either of azeotropic distillation with benzene, as suggested by Thomas (Ref. 11), or of treatment with molecular sieves, as suggested by Ritchie (Ref. 17), and that the resulting DMF is then shaken with Na₂CO₃ or, better, with BaO for 1 or 2 days. After decantation the DMF is distilled twice under nitrogen (pressure <15 torr) using a 1-m column. All these operations must be carried out in the dark. After deaeration the solvent is stored under nitrogen and used as soon as possible.

TESTS FOR PURITY

Owing to its various modes of degradation (hydrolysis, thermal and photochemical decomposition) the principal impurities found in DMF are: dimethylamine, formic acid, hydrogen cyanide, carbon dioxide and carbon monoxide. To this list must be added: water, oxygen, which is quite soluble, and impurities resulting from the purification process.

Conductivity. As stressed earlier, hydrolysis as well as decomposition results in ionic impurities: dimethylammonium formate, carbonate or cyanide. Thus, the conductivity of the solvent is a very good test of its purity.

Experimental conductivities recorded in DMF are always higher than those reported for other aprotic solvents such as ketones or nitriles. According to a rough estimate, the theoretical conductivity of the solvent should be below $10^{-13} \Omega^{-1}\text{cm}^{-1}$. In fact, conductivities obtained by the most careful workers are scarcely ever less than 10^{-7} . The best values have been reported, to our knowledge, by Brummer (Ref. 12) who used for conductometric studies a solvent having conductivities varying from 2×10^{-8} to $5 \times 10^{-8} \Omega^{-1}\text{cm}^{-1}$. Values below 5×10^{-7} have been reported by numerous authors and any batch of DMF which is more conducting can be considered to be impure.

Water. Water can be titrated by the Karl Fischer (K-F) reagent. Kanatharan (Ref. 22) recommends that the titration is conducted slowly, since K-F reagent reacts only slowly with small amounts of water.

Usual procedures do not allow the determination of less than 10 ppm of water. According to Muroi (Ref. 26) it is possible to titrate as little as 0.2 ppm by increasing the sharpness of the end point, using the following procedure: "Add a 10-30 ml sample to 25 ml MeOH containing 8% of a pyridine- SO_2 solution (320 g SO_2 /1 pyridine) and titrate potentiometrically with K-F reagent having a titre of 0.1-0.5 mg $\text{H}_2\text{O}/\text{ml}$ ". The use of DMF as a solvent for K-F reagent also has been advocated (Ref. 27).

Prue (Ref. 23) has titrated water in DMF using triphenylsilyl chloride, from which, according to Thomas (Ref. 11), hydrogen chloride is liberated quantitatively by water (amines or acids are thought to interfere); the HCl content is then estimated from the conductivity of the solution.

It is quite easy to prepare a solvent which contains less than 50 ppm of water. Very low concentrations ($< 5\text{ppm}$) are more difficult to attain. The best value, less than 3 ppm, has been reported by Libbey and Stock (Ref. 28).

Dimethylamine. Colorimetric methods have been used by some authors. In our opinion, as long as the autoprotolysis constant of the solvent is not known, it is not possible to say exactly what is basic and what is acidic in DMF. Kolthoff (Ref. 24) has used p-nitrophenol in the colorimetric determination of total basicity, but specific determinations would be preferable.

Thomas and Rochow (Ref. 11) have based the determination of the amine content on the fact that dimethylamine forms with 1-fluoro-2,4-dinitrobenzene a complex which absorbs in the visible spectrum at 3812 Å. Solvent prepared by Chang and Criss (Ref. 29) was found to contain less than 1 ppm of dimethylamine using this method.

Another spectrophotometric method which allows the determination of the dimethylamine content down to 2 ppm with an error of $\pm 10\%$ has been proposed by Pribyl (Ref. 30); dimethyldithiocarbamate, which absorbs at 445 nm, is formed by adding CS_2 and $\text{Cu}(\text{AcO})_2$ to an EtOH-pyridine mixture.

Chromatography was thought by Butler (Ref. 18) not to be a reliable means of establishing the organic impurity content of the solvent since DMF can decompose or hydrolyze at high temperatures. Nevertheless, careful studies of the proper experimental conditions have been undertaken (Ref. 31 and 32). In the paper by Filippov (Ref. 32) it is shown that dimethylamine can be determined in DMF at levels as low as 1 ppm using tetrahydroxyethylenediamine as a stationary phase, polysorb-1 as a solid support and a column temperature of 75°C .

Dimethylamine is not electroactive with mercury but can give coordination compounds with cations which will affect the course of electrochemical reductions.

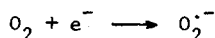
Formic Acid. In contrast to dimethylamine, formic acid is electroactive. Kanatharan and Spritzer (Ref. 22) have attributed to formic acid two peaks, one cathodic, the other anodic, which appear in cyclic voltammograms of aqueous dimethylformamide. Alternating current polarography (Ref. 33), and, better, pulse polarography, can be used to estimate the formic acid content.

Formic acid can also be determined by titration with a base. Potentiometric titration is preferred since it allows determination of the dimethylammonium formate content as well. Megliskii (Ref. 34) has titrated potentiometrically formic acid, dimethylamine and dimethylammonium formate in DMF using two solutions: 0.1 M HClO₄ and 0.1 M KOH, both in alcohol. Such a method is suitable only for concentrations of the order of at least 100 ppm.

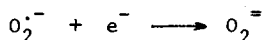
Hydrogen Cyanide. Trisler et al. (Ref. 5) reported the presence of HCN in DMF distilled over CaH₂ in natural light. Concentrations ranged from 10⁻⁵ to 10⁻³ M. Spectrophotometric titration can be carried out with 4-nitrobenzil, which reacts with cyanide ion to form a deep violet ion.

Oxygen. Oxygen is rather soluble in DMF. A study of oxygen solubility in relation to the oxygen content of the gas phase has been made by James (Ref. 35). When the gas phase was air and pure oxygen, the solubility was 2.2 x 10⁻³ and 3.1 x 10⁻³ M, respectively.

Oxygen is an electroactive impurity which interferes in polarography and other electrochemical processes. Two waves are observed (Ref. 36) with E_{1/2} = -0.8 and -2.8 V vs. SCE; the first corresponds to the reduction of oxygen to superoxide:



and the second one to the reduction of superoxide to peroxide ion:



James (Ref. 35) has proposed two methods for the determination of the oxygen concentration; polarography and the Winkler method. Polarographic measurements are made at -1.2 V vs. SCE, in order to ensure that the measured diffusion current is not influenced by a polarographic maximum. A modified Winkler method allows concentrations as low as 10 ppm to be determined. It depends upon quantitative oxidation of iodide ion to iodine. Such a process is described in some detail (Ref. 35).

PHYSICAL PROPERTIES OF DIMETHYLFORMAMIDE

Numerical values of physical constants are highly dependent on the purity of the solvent. Consequently, important discrepancies are found in the literature. The present recommended values result from a careful examination of three aspects: accuracy of the measurements, consistency of the data of various authors at different temperatures, and purification of the solvent. Such a choice is subject to personal evaluation and it seems prudent to give also the other references.

Density. The density is probably a good criterion of the purity of the solvent. Contamination with water increases the density (Ref. 23). The following values of the density at 25°C have been found (Ref. 23,8,37,12): 0.9439, 0.9440₂, 0.9441₅ and 0.9442 g cm⁻³, respectively. Old values greater than 0.9443 frequently found in tables are probably too high. New work by Kawaizumi and Zana (Ref. 38) seems to indicate that the density of the pure solvent is lower. These authors obtain values ranging from 0.94360 to 0.94368. It is our feeling that these data are more accurate than previous ones but such a low value (ρ = 0.94364 ± 0.00004) must be confirmed by others before being accepted.

Values at various temperatures other than those appearing in Table 2 have been given by Gopal and Rizvi (Ref. 39). At 20°C Saphon (Ref. 40) has obtained ρ = 0.94878 g cm⁻³, in good agreement with the value in Table 2.

TABLE 2. Recommended values for physical constants of DMF at various temperatures

		ρ g cm ⁻³	η poise	D
Temperature	20°C	0.9488	0.00845	38
	30°C	0.9394	0.00746	36.1
	40°C	0.9298	0.00664	34.4
	50°C	0.9202	0.00598	32.8
Reference		12	49	1

Viscosity. Other values can be found in References (29) and (41). Prue's data at 25°C are confirmed by measurements reported by Ames and Sears (Ref. 42).

Dielectric constant. Data given by Bass and Cole (Ref. 1) are preferred to previous results (Ref. 43) of Leader and Gormley (36.71 at 25°C). The value reported at 25°C is interpolated from measurements at various temperatures. Data of Saphon (Ref. 40) are in good agreement with the value reported in Table 2 at 20°C ($D = 38.13$).

Miscellaneous. Data at various temperatures concerning refractive index, surface tension and isothermal compressibility can be found in Refs. (44), (45) and (12), respectively. Other data concerning thermodynamic properties are reported in Refs. (39) and (44). Plots of vapor pressure, heat of vaporization, heat capacity, density, viscosity, surface tension and thermal conductivity for a large range of temperature have been drawn up by Gallant (Ref. 46). The solubilities of some sixty substances in DMF have been tabulated (Ref. 50). Organic reactions in or with DMF have been summarized (Ref. 51).

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Exhibit 31

FDA Updates and Press Announcements on Angiotensin II Receptor Blocker (ARB) Recalls (Valsartan, Losartan, and Irbesartan)

Get updates on the recalls

Update: 11/13/2019 - FDA warns Mylan for CGMP deviations

Update [11/13/2019] Today, the U.S. Food and Drug Administration posted a [warning letter \(/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/mylan-laboratories-limited-unit-8-589297-11052019\)](#) to Mylan Pharmaceuticals, Inc. in Chodavaram Village, Vizianagaram, Andhra Pradesh, India. Mylan manufactures valsartan active pharmaceutical ingredient (API) and has been one subject of an ongoing global investigation into nitrosamine impurities in angiotensin II receptor blockers (ARBs) such as valsartan, losartan and irbesartan.

The warning letter outlines several current good manufacturing practice (CGMP) deviations at this Mylan facility, including failure to have adequate written procedures for the receipt, identification and handling of raw materials and failure to adequately clean equipment and utensils. Failure to correct these deviations may result in further action by the agency. The warning letter is another result of the agency's ongoing investigation.

FDA reminds patients taking recalled ARBs to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

Update: 10/15/2019 - FDA warns Torrent for CGMP violations

Update [10/15/2019] Today, the U.S. Food and Drug Administration posted a [warning letter \(/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/torrent-pharmaceuticals-limited-585255-10082019\)](#) to Torrent Pharmaceuticals in Ahmedabad, Gujarat, India. Torrent manufactures losartan potassium tablets and has been one subject of an ongoing global investigation into nitrosamine impurities in angiotensin II receptor blockers (ARBs) such as valsartan, losartan and irbesartan.

The warning letter outlines several manufacturing violations at Torrent's Taluka-Kadi, Indrad, Gujarat facility, including failure to follow written procedures for production and process control and failure to adequately investigate batch discrepancies. Failure to correct these violations may result in further action by the agency. The warning letter is another result of the agency's ongoing investigation.

FDA reminds patients taking recalled ARBs to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

Update: 9/20/2019 - Torrent expands its voluntary recall of losartan

Update [9/20/2019] Torrent Pharmaceuticals is expanding its voluntary [recall \(/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-o\)](#) to include five additional lots of losartan potassium tablets (three lots of losartan potassium tablets and two lots of losartan potassium/hydrochlorothiazide (HCTZ) combination tablets). This recall is due to unacceptable amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in the losartan active pharmaceutical ingredient manufactured by Hetero Labs Limited. Torrent is recalling lots of losartan-containing medication that tested positive for NMBA above 9.82 parts per million.

The agency updated the list of [recalled angiotensin II receptor blockers \(ARBs\) \(/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and\)](#) accordingly.

FDA reminds patients taking recalled ARBs to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

8/28/2019: STATEMENT: Statement on the agency's ongoing efforts to resolve safety issue with ARB medications

Go to [FDA Statement \(/news-events/press-announcements/statement-agencys-ongoing-efforts-resolve-safety-issue-arb-medications\)](#).

6/26/2019: UPDATE - Macleods Pharmaceuticals voluntarily recalls losartan containing NMBA

Update [6/26/2019] FDA is alerting patients and health care professionals to Macleods Pharmaceuticals' voluntary [recall](/safety/recalls-market-withdrawals-safety-alerts/macleods-pharmaceutical-limited-issues-voluntary-nationwide-consumer-level-recall-losartan-potassium) of two lots of losartan potassium tablets (50mg strength) and 30 lots of losartan potassium/hydrochlorothiazide (HCTZ) combination tablets (12 lots of 50mg/12.5mg strength, three lots of 100mg/12.5mg strength, and 15 lots of 100mg/25mg strength). This recall is due to unacceptable amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in the losartan active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

FDA is working with manufacturers to reduce and remove nitrosamines from angiotensin II receptor blockers (ARBs). The agency also updated the list of [recalled angiotensin II receptor blockers \(ARBs\)](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and).

FDA reminds patients taking recalled ARBs to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

6/12/2019: UPDATE - Teva expands its voluntary recall of losartan

Update [6/12/2019] Teva Pharmaceuticals is expanding its voluntary [recall](/safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-expands-voluntary-nationwide-recall-losartan-potassium-50-mg-and-100-mg) to include seven additional lots of losartan potassium tablets (three lots of 50 mg strength and four lots of 100 mg strength) labeled by Golden State Medical Supply. This recall is due to unacceptable amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in the losartan active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited. Teva is recalling lots of losartan-containing medication that tested positive for NMBA above 9.82 parts per million.

The agency updated the list of [recalled angiotensin II receptor blockers \(ARBs\)](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and), accordingly.

FDA reminds patients taking recalled ARBs to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

5/6/2019: UPDATE - FDA alerts patients and health care professionals to Vivimed's recall of losartan medication due to NMBA

Update [5/6/2019] FDA is alerting patients and health care professionals to a voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/vivimed-life-sciences-pvt-ltd-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-50-mg-and>) of 19 lots of losartan potassium tablets made by Vivimed Life Sciences Pvt Ltd in Alathur, Chennai, India and distributed by Heritage Pharmaceuticals Inc, East Brunswick, New Jersey, due to the detection of the impurity N-Nitroso-N-methyl-4-aminobutyric acid (NMBA). Vivimed is recalling lots of losartan-containing medication that tested positive for NMBA above 9.82 parts per million.

Manufacturers should contact FDA's Drug Shortages Staff when their testing of losartan shows levels of NMBA that exceed the [interim acceptable intake limit](https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan#interimlimits2) (<https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-angiotensin-ii-receptor-blocker-arb-recalls-valsartan-losartan#interimlimits2>) of 0.96 ppm. FDA will determine, on a case-by-case basis, whether lots containing NMBA greater than 0.96 ppm should be released for distribution.

FDA reminds patients taking recalled angiotensin II receptor blockers (ARBs) to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

The agency also updated the [list of recalled ARBs](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and) (</drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and>).

5/2/2019: UPDATE - Laboratory analysis of valsartan products

Update [5/2/2019] FDA posted [laboratory test results showing NDEA levels in recalled valsartan products](/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products) (</drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products>) as well as an assessment of the cancer risk from NDEA in valsartan.

4/29/2019: UPDATE - FDA alerts patients and health care professionals to Teva's recall and Legacy's expanded recall of losartan medication due to NMBA

Update [4/29/2019] FDA is alerting patients and health care professionals to a voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/teva-pharmaceuticals-usa-inc-issues-voluntary-nationwide-recall-losartan-potassium-25-mg-and-100-mg>) of 44 lots of losartan potassium tablets manufactured by Teva Pharmaceuticals and labeled as Golden State Medical Supply due to the detection of the impurity N-Nitroso-N-methyl-4-

aminobutyric acid (NMBA). The recalled products were made with active pharmaceutical ingredient (API) manufactured by Hetero Labs. Teva is recalling lots of losartan-containing medication that tested positive for NMBA above 9.82 parts per million.

Additionally, Legacy expanded its [recall \(/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-expands-voluntary-nationwide-recall-losartan-potassium-tablets\)](/safety/recalls-market-withdrawals-safety-alerts/legacy-pharmaceutical-packaging-llc-expands-voluntary-nationwide-recall-losartan-potassium-tablets) to include one additional lot of losartan tablets made with API manufactured by Hetero Labs.

Manufacturers should contact FDA's Drug Shortages Staff when their testing of losartan shows levels of NMBA that exceed the interim acceptable intake limit of 0.96 ppm. FDA will determine, on a case-by-case basis, whether lots containing NMBA greater than 0.96 ppm should be released for distribution.

The agency also updated the list of [recalled losartan medicines \(/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and\)](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and).

4/19/2019: UPDATE - Torrent further expands its voluntary recall of losartan; FDA posts new nitrosamine testing methods

Update [4/19/2019] Torrent Pharmaceuticals Limited is further expanding its voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium>) to include 104 additional lots of losartan potassium and losartan potassium/hydrochlorothiazide combination tablets. This recall is due to unacceptable amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in the losartan active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

The agency updated the list of [losartan products under recall \(/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and\)](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and) accordingly.

FDA reminds patients taking recalled angiotensin II receptor blockers (ARBs) to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition.

FDA is also posting new testing methods which can help manufacturers and international regulators detect and identify multiple nitrosamine impurities. FDA and international regulators have identified N-Nitrosodimethylamine (NDMA), N-Nitrosodiethylamine (NDEA) and NMBA in ARBs.

- A [direct injection GC-MS method \(/media/123409/download\)](/media/123409/download) that is able to detect NDMA, NDEA, N-Nitrosodiisopropylamine (NDIPA), N-Nitrosoethylisopropylamine

(NEIPA), and N-nitrosodibutylamine (NDBA)

- A [headspace GC-MS method \(/media/124025/download\)](/media/124025/download) that is able to detect NDMA, NDEA, NDIPA, and NEIPA

These methods should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

4/4/2019: STATEMENT - Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the agency's list of known nitrosamine-free valsartan and ARB class medicines, as part of agency's ongoing efforts to resolve ongoing safety issue

Go to [FDA Statement \(/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys\)](/news-events/press-announcements/fda-statement-agencys-list-known-nitrosamine-free-valsartan-and-arb-class-medicines-part-agencys).

3/22/2019: UPDATE - FDA updates recalled valsartan-containing and losartan-containing medicine information

Update [3/22/2019] FDA has updated the [list of valsartan medicines under recall \(/media/118231/download\)](/media/118231/download) to incorporate additional repackagers of Aurobindo's valsartan-containing medicine. FDA has also updated the [list of losartan medicines under recall \(/media/119422/download\)](/media/119422/download) to include repackagers of Torrent's and Camber's losartan-containing medicines.

The agency also updated the [list of valsartan medicines not under recall \(/media/118232/download\)](/media/118232/download) accordingly.

3/20/2019: UPDATE - FDA not objecting to losartan with NMBA below 9.82 ppm remaining on the market

Update [3/20/2019] To ensure patient access to losartan, FDA will not object to certain manufacturers temporarily distributing losartan containing N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) above the [interim acceptable intake limit](#) of 0.96 parts per million (ppm) and below 9.82 ppm until the impurity can be eliminated. The agency expects many companies will be able to manufacture losartan without nitrosamine impurities and replenish the U.S. supply in approximately six months.


Agency scientists evaluated the risk of exposure to NMBA at levels up to 9.82 ppm and determined that it presents no meaningful difference in cancer risk over a six-month time period when compared to a lifetime of exposure to NMBA at 0.96 ppm. Distributing losartan containing NMBA up to 9.82 ppm, will help maintain adequate losartan supply while companies obtain approval for manufacturing processes that produce nitrosamine-free losartan for patients.


FDA reminds patients taking recalled losartan to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition. Untreated hypertension (high blood pressure) leads to an increase in the risk of heart attacks and stroke. Untreated heart failure increases the risk of hospitalization and death. Untreated diabetic nephropathy (kidney disease) leads to worsening renal (kidney) disease.

Manufacturers should contact FDA's Drug Shortages Staff when their testing of losartan shows levels of NMBA that exceed the interim acceptable intake limit of 0.96 ppm. FDA will determine, on a case-by-case basis, whether lots containing NMBA greater than 0.96 ppm should be released for distribution.

FDA continues to work with companies and international regulators to ensure products entering the U.S. market do not contain nitrosamine impurities.

3/1/2019: UPDATE - Torrent again expands its voluntary recall of losartan; Hetero also voluntarily recalls losartan

Update [3/1/2019] Torrent Pharmaceuticals Limited is further expanding its voluntary recall (<https://public4.pagefreezer.com/browse/FDA/02-07-2022T12:48/https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium-o>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) to include 114 additional lots of losartan potassium and losartan potassium/hydrochlorothiazide combination tablets. This recall is due to unacceptable amounts of N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) in the losartan active pharmaceutical ingredient manufactured by Hetero Labs Limited.

Today, the agency also issued a press release (<https://public4.pagefreezer.com/browse/FDA/28-06-2022T09:52/https://www.fda.gov/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-arb-drug-products-reports-finding-new-nitrosamine>)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) to provide additional information about its ongoing investigation and another voluntary recall by Hetero/Camber

Pharmaceuticals, which was announced on February 28, of 87 lots of losartan potassium tablets (25 mg, 50 mg and 100 mg). The recalled losartan potassium and losartan potassium/hydrochlorothiazide tablets are also manufactured by Hetero, which are distributed by Camber, and contain the impurity NMBA.

Torrent and Hetero/Camber are only recalling lots of losartan-containing medication with NMBA above the interim acceptable intake limits of 0.96 parts per million (ppm).

The agency also updated the list of losartan products under recall (</media/119422/download>).

3/1/2019: UPDATE - Aurobindo expands its voluntary recall of valsartan and amlodipine/valsartan

Update [3/1/2019] AurobindoPharma USA is expanding its voluntary recall (AurobindoPharma USA, Inc. Initiates a Voluntary Nationwide Consumer Level Recall Expansion of 38 Lots of Amlodipine Valsartan Tablets USP and Valsartan Tablets, USP due to the detection of NDEA (N-Nitrosodiethylamine) Impurity.) to include 38 additional lots of valsartan and amlodipine/valsartan combination tablets. The recall is due to unacceptable amounts of N-Nitrosodiethylamine (NDEA) found in the medicine.

Aurobindo is only recalling lots of valsartan-containing medication where NDEA has been detected above the interim acceptable intake limit of 0.083 parts per million. FDA is working with manufacturers to reduce and remove nitrosamines from angiotensin II receptor blockers (ARBs).

The agency also updated the valsartan products under recall (</media/118231/download>).

3/1/2019: PRESS RELEASE - FDA provides update on its ongoing investigation into ARB drug products; reports on finding of a new nitrosamine impurity in certain lots of losartan and product recall

Go to Press Release

(<https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm632425.htm>).

FDA updates table of interim limits for nitrosamine impurities in ARBs

Update [2/28/2019] FDA is posting the updated table of interim acceptable intake limits for nitrosamine impurities to reflect N-Nitroso-N-methyl-4-aminobutyric acid (NMBA) limits, which are the same as those for NDMA.

The agency will use the interim limits below to recommend manufacturers conduct a voluntary recall if laboratory testing confirms the presence of nitrosamine impurities in finished drug product. FDA is working with industry and international regulators to ensure products entering the market do not contain these impurities, but we are tolerating the impurities below the level established in the table for a short period of time to avoid a possible shortage of ARBs.

Not all ARB products contain NDMA, NDEA or NMBA impurities, so pharmacists may be able to provide an alternative medication not affected by the recalls, or health care professionals may prescribe a different medication that treats the same condition.

Interim Limits for NDMA, NDEA, and NMBA in Angiotensin II Receptor Blockers (ARBs)

Drug	Maximum Daily Dose (mg/day)	Acceptable Intake NDMA (ng/day)*	Acceptable Intake NDMA (ppm)**	Acceptable Intake NDEA (ng/day)*	Acceptable Intake NDEA (ppm)**	Acceptable Intake NMBA (ng/day)*	Acceptable Intake NMBA (ppm)**
Valsartan	320	96	0.3	26.5	0.083	96	0.3
Losartan	100	96	0.96	26.5	0.27	96	0.96***
Irbesartan	300	96	0.32	26.5	0.088	96	0.32
Azilsartan	80	96	1.2	26.5	0.33	96	1.2
Olmesartan	40	96	2.4	26.5	0.66	96	2.4
Eprosartan	800	96	0.12	26.5	0.033	96	0.12
Candesartan	32	96	3.0	26.5	0.83	96	3.0
Telmisartan	80	96	1.2	26.5	0.33	96	1.2

* The acceptable intake is a daily exposure to a compound such as NDMA, NDEA, or NMBA that approximates a 1:100,000 cancer risk after 70 years exposure

** These values are based on a drug's maximum daily dose as reflected in the drug label

*** FDA is temporarily not objecting to losartan with NMBA below 9.82 ppm remaining on the market

2/25/2019: UPDATE - Losartan distributed by Macleods Pharmaceuticals voluntarily recalled

Update [2/25/2019] FDA is alerting patients and health care professionals to a voluntary recall of one lot of losartan potassium/hydrochlorothiazide (HCTZ) 100mg/25mg combination tablets manufactured by Macleods Pharmaceuticals. The recall is due to unacceptable amounts of N-Nitrosodiethylamine (NDEA) found in the medicine made with active pharmaceutical ingredient manufactured by Hetero Labs Limited.

Macleods is only recalling lots of losartan-containing medication where NDEA has been detected above the interim acceptable intake limit of 0.27 parts per million. FDA is working with manufacturers to reduce and remove nitrosamines from angiotensin II receptor blockers (ARBs).

The agency also updated the list of losartan products under recall (</media/119422/download>).

1/25/2019: STATEMENT - Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on the FDA's ongoing investigation into valsartan and ARB class impurities and the agency's steps to address the root causes of the safety issues

Go to FDA Statement (</news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-and-arb-class-impurities-and-agencys-steps>).

1/23/2019: UPDATE - Torrent further expands its voluntary recall of losartan

Update [1/23/2019] Torrent Pharmaceuticals is further expanding its voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium>) to include six additional lots of losartan potassium and hydrochlorothiazide combination tablets, for a total of 16 lots of losartan-containing medicines. This recall is due to unacceptable amounts of N-Nitrosodiethylamine (NDEA) in the losartan active pharmaceutical ingredient manufactured by Hetero Labs Limited.

Torrent is only recalling lots of losartan-containing medication containing NDEA above the interim acceptable intake limits of 0.27 parts per million (ppm).

The agency also updated the list of losartan medications under recall (</media/119422/download>).

1/18/2019: UPDATE - Irbesartan distributed by Solco Healthcare voluntarily recalled

Update [1/18/2019] FDA is alerting patients and health care professionals to a voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/prinston-pharmaceutical-inc-issues-voluntary-nationwide-recall-irbesartan-and-irbesartan-hctz>) of one lot of irbesartan and seven lots of irbesartan and hydrochlorothiazide (HCTZ) combination tablets distributed by Solco Healthcare LLC, a Princeton Pharmaceutical Inc. subsidiary. The recall is due to unacceptable amounts of N-Nitrosodiethylamine (NDEA) in the irbesartan active pharmaceutical ingredient manufactured by Zhejiang Huahai Pharmaceuticals (ZHP).

Solco is only recalling lots of irbesartan-containing medication where NDEA has been detected above the interim limit of 0.088 parts per million. FDA is working with manufacturers to reduce and remove nitrosamines from angiotensin receptor II blockers (ARBs).

The agency also updated the list of irbesartan products under recall.

1/3/2019: UPDATE - Torrent expands its voluntary recall of losartan

Update [1/3/2019] Torrent Pharmaceuticals is expanding its voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-expands-voluntary-nationwide-recall-losartan-potassium-tablets-usp>) to include eight additional lots of losartan potassium tablets, for a total of 10 lots. This recall is due to trace amounts of N-Nitrosodiethylamine (NDEA) in the losartan active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

Torrent is only recalling lots of losartan medication containing NDEA above the interim acceptable intake level of 0.27 parts per million.

The agency also updated the list of list of valsartan products under recall (</media/118231/download>).

1/2/2019: UPDATE - FDA alerts patients and health care professionals to Aurobindo's recall of valsartan medication due to NDEA

Update [1/2/2019] FDA is alerting patients and health care professionals to Aurobindo Pharma USA's voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-usa-inc-initiates-voluntary-nationwide-consumer-level-recall-80-lots-amlodipine>) of two lots of valsartan tablets, 26 lots of amlodipine and valsartan combination tablets, and 52 lots of valsartan and hydrochlorothiazide (HCTZ) combination tablets due to the amount of N-Nitrosodiethylamine (NDEA) in the valsartan active

pharmaceutical ingredient. Aurobindo is recalling amlodipine and HCTZ only in combination medications containing valsartan. Neither amlodipine nor HCTZ is currently under recall by itself.

Aurobindo is recalling lots of valsartan-containing medication that tested positive for NDEA above the interim acceptable daily intake level of 0.083 parts per million.

The agency continues to investigate and test all angiotensin II receptor blockers (ARBs) for the presence of NDEA and N-Nitrosodimethylamine (NDMA) and is taking swift action when it identifies these impurities that are above interim acceptable daily intake levels.

FDA also updated the [list of valsartan products under recall \(/media/118231/download\)](/media/118231/download) and the [list of valsartan products not under recall \(/media/118232/download\)](/media/118232/download).

FDA reminds patients taking any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor prescribes a different medication that treats the same condition. Some ARBs contain no NDMA or NDEA.

12/20/2018: UPDATE - FDA alerts patients and health care professionals to Torrent's recall of losartan medication due to NDEA

Update [12/20/2018] FDA is alerting patients and health care professionals to Torrent Pharmaceuticals'

voluntary [recall \(/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium\)](/safety/recalls-market-withdrawals-safety-alerts/updated-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-losartan-potassium) of two lots of losartan potassium 100 mg tablets due to N-Nitrosodiethylamine (NDEA) in the losartan active pharmaceutical ingredient (API) manufactured by Hetero Labs Limited.

Not all Torrent losartan-containing medications distributed in the U.S. are being recalled. Torrent is recalling only those lots of losartan medication that tested positive for NDEA above the acceptable daily intake of 0.27 ppm.

The agency continues to investigate and test all angiotensin II receptor blockers (ARBs) for the presence of NDEA and N-Nitrosodimethylamine (NDMA) and is taking swift action when it identifies these impurities that are above acceptable daily intake levels.

FDA posted a list of [losartan medications under recall \(/media/119422/download\)](/media/119422/download). Additionally, FDA reminds patients taking this medication or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain

NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

12/19/2018: UPDATE - FDA presents interim limits of nitrosamines in currently marketed ARBs

Update [12/19/2018] FDA is publishing interim acceptable intake levels of nitrosamine impurities in angiotensin II receptor blockers (ARBs) for manufacturers to use to ensure their finished drug products are safe for patients.

The agency evaluated safety data for N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) to determine an interim acceptable intake level for these impurities in the ARB class. NDMA and NDEA are probable human carcinogens and should not be present in drug products. We are currently aware of NDMA and NDEA in certain valsartan, irbesartan and losartan-containing products, and those products and some active pharmaceutical ingredients (API) used to manufacture them have been recalled from the U.S. market. See the [list of valsartan products under recall \(/media/118231/download\)](/media/118231/download), and the [list of irbesartan products under recall \(/media/118233/download\)](/media/118233/download).

Drug products that contain NDMA or NDEA above the limits in the table below pose an unacceptable risk to patients. The agency will use the interim limits to recommend manufacturers conduct a voluntary recall if laboratory testing confirms the presence of nitrosamine impurities in finished drug product. FDA is working with industry and international regulators to ensure products entering the market do not contain these impurities, but we are tolerating the impurities below the level established in the table for a short period of time to avoid a possible shortage of ARBs.

The agency reminds manufacturers they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects a new impurity or higher level of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients. To aid industry and regulatory agencies, FDA has developed and published methods to detect NDMA and NDEA impurities – the gas chromatography/mass spectrometry (GC/MS) headspace method (</media/115965/download>), the [combined GC/MS headspace method \(/media/117843/download\)](/media/117843/download), and the [combined GC/MS direct injection method \(/media/117807/download\)](/media/117807/download). These methods can be used for drug substances and products, and users should validate them as part of good manufacturing practices and where data are used to support a regulatory submission or required quality assessment of the API or drug product.

Not all ARB products contain NDMA or NDEA impurities, so pharmacists may be able to provide an alternative medication not affected by the recalls, or health care professionals may prescribe a different medication that treats the same condition.

Interim Limits for NDMA and NDEA in Angiotensin II Receptor Blockers (ARBs)

Drug	Maximum Daily Dose (mg/day)	Acceptable Intake NDMA (ng/day)*	Acceptable Intake NDMA (ppm)**	Acceptable Intake NDEA (ng/day)*	Acceptable Intake NDEA (ppm)**
Valsartan	320	96	0.3	26.5	0.083
Losartan	100	96	0.96	26.5	0.27
Irbesartan	300	96	0.32	26.5	0.088
Azilsartan	80	96	1.2	26.5	0.33
Olmesartan	40	96	2.4	26.5	0.66
Eprosartan	800	96	0.12	26.5	0.033
Candesartan	32	96	3.0	26.5	0.83
Telmisartan	80	96	1.2	26.5	0.33

* The acceptable intake is a daily exposure to a compound such as NDMA or NDEA that results in a 1:100,000 cancer risk after 70 years exposure

** These values are based on a drug's maximum daily dose as reflected in the drug label

For comparison with the levels of NDMA found in some common foods, please see our Aug. 20, 2018, update.

12/12/2018: UPDATE - FDA updates NDMA and NDEA detection methods, announces posting of ZHP warning letter

Update [12/12/2018] The FDA has updated its testing methods to detect NDMA and NDEA impurities – the [GC/MS\) headspace method \(/media/115965/download\)](https://www.fda.gov/media/115965/download), the [combined headspace method \(/media/117843/download\)](https://www.fda.gov/media/117843/download), and the [combined direct injection method \(/media/117807/download\)](https://www.fda.gov/media/117807/download) – by adding the limits of detection (LOD) and clarifying that the methods can be used for both drug substances and drug products. These methods were

validated with respect to valsartan drug substances and drug products, but the agency expects them to have comparable LODs and limits of quantitation (LOQ) for other angiotensin II receptor blockers (ARB).

The agency also issued a press release announcing the posting of a warning letter the agency issued Nov. 29 to Zhejiang Huahai Pharmaceuticals Co. Ltd. (ZHP).

12/11/2018: PRESS RELEASE - FDA warns API manufacturer involved in valsartan recall, provides information for patients taking these medications

Go to [Press Release \(/news-events/press-announcements/fda-warns-api-manufacturer-involved-valsartan-recall-provides-information-patients-taking-these\)](/news-events/press-announcements/fda-warns-api-manufacturer-involved-valsartan-recall-provides-information-patients-taking-these).

12/6/2018: UPDATE - Mylan expands its voluntary recall of valsartan-containing products

Update [12/6/2018] Mylan Pharmaceuticals is expanding its voluntary recall [\(\[!-\\$_wcmUrl\('link','UCM627647'\)--\]\)](#) to include all lots of non-expired valsartan-containing products due to trace amounts of N-Nitrosodiethylamine (NDEA) in the valsartan active pharmaceutical ingredient (API) manufactured by Mylan Laboratories Limited. The 104 additional lots include 26 lots of amlodipine and valsartan tablets, 51 lots of valsartan tablets and 27 lots of valsartan and hydrochlorothiazide tablets. These lots were distributed in the U.S. between March 2017 and November 2018.

The agency also updated the [list of valsartan products under recall \(/media/118231/download\)](#) and the [list of valsartan products not under recall \(/media/118232/download\)](#).

11/27/2018: UPDATE - FDA alerts patients and health care professionals to Teva's recall of valsartan products due to NDEA

Update [11/27/2018] FDA is alerting patients and health care professionals to Teva Pharmaceuticals' voluntary [recall \(/safety/recalls-market-withdrawals-safety-alerts\)](/safety/recalls-market-withdrawals-safety-alerts) of valsartan-containing products manufactured using active pharmaceutical ingredient (API) from Mylan Pharmaceuticals. Mylan voluntarily [recalled \(/safety/recalls-market-withdrawals-safety-alerts\)](/safety/recalls-market-withdrawals-safety-alerts) valsartan-containing products on November 20.

Teva is recalling all lots of amlodipine and valsartan combination tablets and amlodipine, valsartan, and hydrochlorothiazide (HCTZ) combination tablets due to the presence of N-Nitrosodiethylamine (NDEA). Teva has recalled other valsartan-containing products in

recent months due to the presence of N-Nitrosodimethylamine (NDMA). With this recall, Teva has now recalled all their unexpired valsartan-containing products from the U.S. market.

The agency continues to investigate and test all angiotensin II receptor blocker (ARBs) for the presence of NDMA and NDEA and is taking swift action when it identifies these impurities that are above acceptable levels.

FDA has updated the [list of valsartan products under recall \(/media/118231/download\)](/media/118231/download) and the [list of valsartan products not under recall \(/media/118232/download\)](/media/118232/download). The agency reminds patients taking this medication or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know that not all ARBs contain NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

11/21/2018: UPDATE - FDA alerts patients and health care professionals to Mylan's recall of valsartan products due to NDEA

Update [11/21/2018] FDA is alerting patients and health care professionals to Mylan Pharmaceuticals' voluntary recall of 15 lots of valsartan-containing products due to the presence of N-Nitrosodiethylamine (NDEA).

Not all Mylan valsartan-containing products distributed in the U.S. are being recalled. Mylan is recalling only those lots of valsartan-containing products that tested positive for NDEA above the acceptable level. The agency continues to investigate and test all angiotensin II receptor blockers (ARBs) for the presence of NDEA and N-Nitrosodimethylamine (NDMA) and is taking swift action when it identifies these impurities that are above acceptable levels.

FDA has updated lists of [valsartan products under recall \(/media/118231/download\)](/media/118231/download) and [valsartan products not under recall \(/media/118232/download\)](/media/118232/download). Additionally, FDA reminds patients taking this medication or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain NDMA or NDEA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

11/9/2018: UPDATE - FDA alerts patients and health care professionals to Sandoz's losartan

potassium and hydrochlorothiazide recall of one lot due to NDEA

Update [11/9/2018] FDA is alerting patients and health care professionals to Sandoz's voluntary recall (</safety/recalls-market-withdrawals-safety-alerts/sandoz-inc-issues-voluntary-nationwide-recall-one-lot-losartan-potassium-and-hydrochlorothiazide-due>) of one lot – JB8912 – of losartan potassium and hydrochlorothiazide 100mg/25mg tablets, that contain losartan, an angiotensin II receptor blocker (ARB), and hydrochlorothiazide, a diuretic, used in combination for the treatment of hypertension. Sandoz's product was made using an active pharmaceutical ingredient (API) that has tested positive for NDEA. The API was manufactured by Zhejiang Huahai Pharmaceutical Co. Ltd, which is on import alert (https://www.accessdata.fda.gov/cms_ia/importalert_189.html).

Sandoz's losartan drug products make up less than 1 percent of the total losartan drug products in the U.S. market.

FDA continues to investigate the presence of NDEA and NDMA, which are probable human carcinogens, in ARBs and is taking swift action when it identifies unacceptable impurities in API and finished drug products.

FDA reminds patients taking this medication or any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. It also is important to know not all ARBs contain NDEA or NDMA, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

10/30/2018: UPDATE - FDA alerts patients and health care professionals to ScieGen's irbesartan recall due to NDEA

Certain irbesartan products labeled as Westminster Pharmaceuticals Inc. and GSMS Inc. recalled

Update [10/30/2018] FDA is alerting patients and health care professionals to ScieGen's voluntary recall of certain lots of irbesartan, an angiotensin II receptor blocker (ARB), because they contain N-Nitrosodiethylamine (NDEA), a known animal and suspected human carcinogen (causes cancer). FDA laboratory testing confirmed NDEA in some lots of ScieGen's irbesartan. ScieGen's irbesartan products are labeled as Westminster Pharmaceuticals and Golden State Medical Supply, Inc. (GSMS). See the list of irbesartan products under recall (</media/117814/download>). This is the first non-valsartan drug product the agency has found to contain the NDEA impurity.

ScieGen's recall affects about 1 percent of the irbesartan drug products in the U.S. market.

Additionally, Aurobindo, which manufactures the active pharmaceutical ingredient (API) for ScieGen's irbesartan products, is [recalling \(/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-limited-issues-voluntary-recall-irbesartan-drug-substance-due-detection-trace\)](/safety/recalls-market-withdrawals-safety-alerts/aurobindo-pharma-limited-issues-voluntary-recall-irbesartan-drug-substance-due-detection-trace) all unexpired lots of its irbesartan API supplied to the U.S. market with NDEA. FDA and Aurobindo laboratory testing confirmed NDEA in certain lots of their irbesartan API.

FDA reminds patients taking any recalled ARB to continue taking their current medicine until their pharmacist provides a replacement or their doctor provides an alternative treatment option. Not all ARBs contain NDEA or N-Nitrosodimethylamine (NDMA), a probable human carcinogen previously found in certain recalled valsartan products, so pharmacists may be able to provide a refill of medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

To date, ScieGen is the only manufacturer of irbesartan drug products found to contain NDEA. FDA continues to test all ARBs for the presence of impurities and has publicly posted two methods for manufacturers and regulatory agencies around the world to test their ARBs for the unexpected NDMA and NDEA impurities. The [combined headspace method \(/media/117843/download\)](/media/117843/download) and the [combined direct injection method \(/media/117807/download\)](/media/117807/download) can detect and quantify NDMA and NDEA simultaneously in ARB API and finished drug products.

FDA continues to work with API and drug manufacturers to ensure their products are not at risk for NDMA or NDEA formation. The agency reminds manufacturers they are responsible for developing and using suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects new or higher levels of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients.

For additional information about ARB products, see:

- [list of valsartan products under recall \(/media/118231/download\)](/media/118231/download).
- [list of valsartan products not under recall \(/media/118232/download\)](/media/118232/download).

10/24/2018: UPDATE - FDA updates recalled valsartan-containing product information

Update [10/24/2018] FDA continues to evaluate valsartan-containing products and other angiotensin II receptor blockers (ARBs), and has updated [the list of products included in the recall \(/media/118231/download\)](/media/118231/download) to add one additional lot of RemedyRepack.

10/16/2018: UPDATE - FDA releases additional NDMA/NDEA detection method

Update [10/16/2018] FDA is posting a gas chromatography-tandem mass spectrometry (GC-MS/MS) method (</media/117807/download>), utilizing liquid injection for detecting the presence of impurities N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in valsartan drug products.

This method provides an additional option for regulators and industry to detect NDMA and NDEA impurities. This method can be used alone or in combination with the combined gas chromatography-mass spectrometry (GC/MS) headspace method (</media/117843/download>), the agency recently posted. Like the previously posted methods, this method should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

10/11/2018: UPDATE - FDA releases method for detection and quantification of both NDMA and NDEA

Update [10/11/2018]] FDA is posting a redeveloped combined gas chromatography-mass spectrometry (GC/MS) headspace (</media/117843/download>), method for detecting the presence of impurities N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) in valsartan drug products.

FDA previously posted a GC/MS method for detection of NDMA in valsartan products. Upon detection of NDEA in valsartan products manufactured by Zhejiang Huahai Pharmaceuticals, FDA redeveloped the testing method so that it can be used to detect and quantify levels of both NDMA and NDEA. This method should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

FDA is also working on a GC/MS direct injection method for detection of NDMA and NDEA. We will post the method when it is available. This will provide an additional option for regulators and industry to use to detect both impurities.

10/5/2018: UPDATE - FDA posts laboratory analysis of NDMA levels in recalled valsartan products

Update [10/5/2018] FDA posted laboratory test results showing NDMA levels in recalled valsartan products. FDA will also post [test results \(/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products\)](/drugs/drug-safety-and-availability/laboratory-analysis-valsartan-products) and an assessment of the cancer risk from NDEA when they are available.

9/28/2018: UPDATE - FDA places Zhejiang Huahai Pharmaceuticals on import alert

Update [9/28/2018] FDA placed Zhejiang Huahai Pharmaceuticals on [import alert \(https://www.accessdata.fda.gov/cms_ia/importalert_189.html\)](https://www.accessdata.fda.gov/cms_ia/importalert_189.html) on September 28, 2018, to protect U.S. patients while the active pharmaceutical ingredient (API) manufacturer fully determines how impurities were introduced into its API and remediates its quality systems. The import alert stops all API made by ZHP and finished drug products made using ZHP's API from legally entering the United States. FDA's action follows a recent [inspection \(/media/117875/download\)](/media/117875/download) at ZHP's facility.

FDA reminds manufacturers that it is their responsibility to develop and use suitable methods to detect impurities, including when they make changes to their manufacturing processes. If a manufacturer detects new or higher levels of impurities, they should fully evaluate the impurities and take action to ensure the product is safe for patients.

9/24/2018: UPDATE - FDA updates recall lists and releases method for the detection and quantification of NDMA in valsartan

Update [9/24/2018] FDA has updated the [list of valsartan products not under recall \(/media/118232/download\)](/media/118232/download) with five Teva products that were not previously on either list.

9/13/2018: PRESS RELEASE - FDA provides update on its ongoing investigation into valsartan products; and reports on the finding of an additional impurity identified in one firm's already recalled products

Go to [Press Release \(/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-valsartan-products-and-reports-finding-additional\)](/news-events/press-announcements/fda-provides-update-its-ongoing-investigation-valsartan-products-and-reports-finding-additional).

8/30/2018: STATEMENT - Statement from FDA Commissioner Scott Gottlieb, M.D., and Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research on FDA's ongoing investigation into valsartan impurities and recalls and an update on FDA's current findings

Go to [FDA Statement \(/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current\)](/news-events/press-announcements/fda-statement-fdas-ongoing-investigation-valsartan-impurities-and-recalls-and-update-fdas-current).

8/24/2018: UPDATE - FDA updates recall lists

Update [8/24/2018] Torrent Pharmaceuticals Limited is expanding its voluntary [recalling](/safety/recalls-market-withdrawals-safety-alerts/updatedadditional-lots-added-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall) (</safety/recalls-market-withdrawals-safety-alerts/updatedadditional-lots-added-torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall>). FDA has updated the [list of valsartan products under recall](/media/118231/download) (</media/118231/download>).

8/22/2018: UPDATE - FDA updates recall lists and releases method for the detection and quantification of NDMA in valsartan

Update [8/22/2018] Torrent Pharmaceuticals Limited is expanding its voluntary recall to all lots of unexpired valsartan-containing drug products due to the detection of NDMA in the active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals.

RemedyRepack, a repackager of Torrent's valsartan/amlodipine/hydrochlorothiazide (HCTZ) tablets, has also recalled.

FDA has updated the [list of valsartan products under recall](/media/118231) (</media/118231>) and the [list of valsartan products not under recall](/media/118232/download) (</media/118232/download>).

Additionally, FDA is releasing a gas chromatography-mass spectrometry (GC/MS) [headspace method](/media/115965/download) (</media/115965/download>) for manufacturers and regulators to detect and quantify NDMA in valsartan API and finished drug products. The agency is using this method to test potential NDMA-containing APIs and drug products. This method should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

8/20/2018: UPDATE - FDA updates recalled valsartan-containing product information and presents NDMA levels in some foods

Update [8/20/2018] FDA is alerting health care professionals and patients that Torrent Pharmaceuticals Limited is voluntarily [recalling](/safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-valsartan-amlodipine-hctz-tablets) (</safety/recalls-market-withdrawals-safety-alerts/torrent-pharmaceuticals-limited-issues-voluntary-nationwide-recall-valsartan-amlodipine-hctz-tablets>). 14 lots of valsartan/amlodipine/hydrochlorothiazide (HCTZ) tablets. Not all Torrent valsartan products distributed in the U.S. are being recalled.

FDA recently learned Torrent used affected valsartan active pharmaceutical ingredient (API) manufactured by Zhejiang Huahai Pharmaceuticals. FDA testing confirmed NDMA in some Torrent products.

To date, Torrent has not received any reports of adverse events related to this recall.

FDA has updated the [list of valsartan products under recall \(/media/118231\)](/media/118231) and the [list of valsartan products not under recall \(/media/118232/download\)](/media/118232/download) to incorporate additional repackagers of Camber's valsartan products and Torrent's recall.

NDMA is a known environmental contaminant. For context, it is found in water and foods including meats, dairy products and vegetables.

**Estimated Range of Daily NDMA Consumption for certain foods
(Recommended daily food consumption rates based on [Dietary Guidelines for Americans 2015-2020](https://health.gov/dietaryguidelines/2015/guidelines/) (<https://health.gov/dietaryguidelines/2015/guidelines/>))**

- Cured meat - 0.004-0.23 micrograms¹
- Smoked meat - 0.004-1.02 micrograms¹
- Grilled meat - 0.006-0.13 micrograms¹
- Bacon - 0.07-0.09 micrograms²
 - In more ordinary terms, for example, one pound of bacon may contain 0.304-0.354 micrograms of NDMA

FDA reminds patients taking valsartan from a recalled lot that they should continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option. Not all valsartan products contain NDMA, so pharmacists may be able to provide a refill of valsartan medication not affected by the recall, or doctors may prescribe a different medication that treats the same condition.

¹ Mavelle, T., B. Bouchikhi, and G. Debry, *The occurrence of volatile N-nitrosamines in French foodstuffs. Food Chemistry*, 1991. 42(3): p. 321-338.

² Park, J., et al., *Distribution of Seven N-Nitrosamines in Food. Toxicol Res*, 2015. 31(3): p. 279-288.

8/9/2018: UPDATE - FDA updates recalled valsartan-containing product information

Update [8/9/2018] FDA has updated the [list of valsartan products under recall \(/media/118231\)](/media/118231) and the [list of valsartan products *not* under recall \(/media/118232/download\)](/media/118232/download) to incorporate recalls of valsartan-containing products manufactured by Hetero Labs Limited, in India, labeled as Camber Pharmaceuticals Inc. Not all Camber valsartan products distributed in the U.S. are being recalled.

Camber Pharmaceuticals is [recalling \(/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-valsartan-tablets-usp-40mg-80mg-160mg\)](/safety/recalls-market-withdrawals-safety-alerts/camber-pharmaceuticals-inc-issues-voluntary-nationwide-recall-valsartan-tablets-usp-40mg-80mg-160mg) certain valsartan tablets because they contain the impurity N-nitrosodimethylamine (NDMA) in the active pharmaceutical ingredient (API). Hetero Labs manufactures the API for the Camber products using a process similar to Zhejiang Huahai Pharmaceuticals.

Test results from Hetero Labs show the amount of NDMA found in its valsartan API exceeds acceptable levels; although it is generally lower than the amount discovered in the API manufactured by Zhejiang.

FDA is testing samples of valsartan API and finished products to confirm the extent and amount of NDMA and help inform the ongoing investigation. The agency has also contacted other manufacturers of valsartan API to determine if their manufacturing processes are at risk for the formation of NDMA, and is working with them to ensure NDMA is not present in future valsartan API.

Valsartan is an angiotensin II receptor blocker (ARB), and FDA is investigating whether other types of ARBs are at risk for the presence of NDMA.

Recalled valsartan products labeled as Camber may be repackaged by other companies. FDA will provide updates as more information becomes available.

8/2/2018: UPDATE - FDA updates recalled valsartan-containing product information and reminds API manufacturers to evaluate processes for unsafe impurities

Update [8/2/2018] FDA continues to evaluate valsartan-containing products and has updated the [list of products included in the recall \(/media/118231/download\)](/media/118231/download) and the [list of products *not* included in the recall \(/media/118232/download\)](/media/118232/download). In addition to updating the lists, FDA revised information related to A-S Medication on the list of products included in the recall. The agency will continue to provide information when it becomes available.

FDA is working with drug manufacturers to ensure future valsartan active pharmaceutical ingredients (APIs) are not at risk of NDMA formation. The agency reminds manufacturers to thoroughly evaluate their API manufacturing processes, and changes to those processes,

to detect any unsafe impurities. If a manufacturer detects new or higher levels of impurity, they should take action to prevent changes to the product's safety profile.

7/27/2018: UPDATE - FDA updates recalled valsartan-containing product information

Update [7/27/2018] FDA is updating health care professionals and patients after discovering that several additional companies that repackage drug products are also recalling valsartan-containing products.

FDA has product recall information from three additional repackagers of valsartan-containing products made by Teva Pharmaceuticals and Princeton Pharmaceuticals Inc. – labeled as A-S Medication Solutions LLC, AvKARE and RemedyRepack – and the agency has added them to the recalled products list. Two of these companies, A-S Medication and RemedyRepack, may also distribute valsartan products not affected by the recall. The agency is confirming this information and will provide an update once it is available.

The following additional repackagers are recalling or are expected to recall valsartan-containing products. FDA is working to gather product recall information from these companies and has removed them from the list of products that are not impacted by this recall:

- Bryant Ranch Prepack Inc.
- H. J. Harkins Company Inc. (*this company was not originally included on either list*)
- Lake Erie Medical, doing business as Quality Care Products LLC
- NuCare Pharmaceuticals Inc.
- Northwind Pharmaceuticals
- Proficient Rx

It is possible that not all valsartan-containing products repackaged by these companies are impacted by the recall. **FDA continues to evaluate valsartan-containing products** and will update the [list of products included in the recall \(/media/118231/download\)](/media/118231/download) and the [list of products not included in the recall \(/media/118232/download\)](/media/118232/download) as more information becomes available.

7/27/2018: UPDATE - Analysis of N-nitrosodimethylamine (NDMA) Levels in Recalled Valsartan in the U.S.

Update [7/27/2018] On July 13th, FDA announced a recall of certain batches of valsartan tablets because of an impurity, a chemical known as N-nitrosodimethylamine (NDMA). Valsartan is a medication commonly used to treat high blood pressure and heart failure.

NDMA has been found to increase the occurrence of cancer in animal studies. These animal studies were done using amounts of NDMA much higher than the impurity levels in recalled valsartan batches. Based on these animal studies, the U.S. Environmental Protection Agency considers NDMA a probable human carcinogen (https://www.epa.gov/sites/production/files/2017-10/documents/ndma_fact_sheet_update_9-15-17_508.pdf),—a chemical that can increase the risk of cancer in humans. NDMA is found in some water supplies and in some foods¹. Consuming up to 96 nanograms NDMA/day is considered reasonably safe for human ingestion². It is estimated that over the course of a person's lifetime, consuming this amount of NDMA would result in less than one additional case of cancer for every 100,000 people. To put this in context, currently one out of every three people in the US will experience cancer in their lifetime.

The amounts of NDMA found in the recalled batches of valsartan exceeded these acceptable levels. The agency wanted to put some context around the actual potential risk posed to patients who used versions of valsartan that may have contained high levels of NDMA. Based on records from the manufacturer of the recalled valsartan, some levels of the impurity may have been in the valsartan-containing products for as long as four years. FDA scientists estimate that if 8,000 people took the highest valsartan dose (320 mg) from the recalled batches daily for the full four years, there may be one additional case of cancer over the lifetimes of these 8,000 people. This assessment led to FDA's decision to have these batches recalled.

Patients taking valsartan from a recalled batch should continue taking their current medicine until their doctor or pharmacist provides a replacement or a different treatment option. It is important to know that not all valsartan products contained NDMA, so pharmacists may be able to provide a refill of valsartan medication from batches that are not affected by the recall, or doctors may prescribe a different medication that treats the same indications.

FDA continues to evaluate the safety of valsartan-containing products and will update the list of products included in the recall (</media/118231/download>) and the list of products not included in the recall (</media/118232/download>) as more information becomes available. If you are taking a valsartan product, be sure to check to back as the lists may change.

¹ From Toxnet: <https://toxnet.nlm.nih.gov/> (<https://toxnet.nlm.nih.gov/>).

Average Daily Intake: WATER: (assume 3 to 6 ng N-nitrosodimethylamine/l)(1) 6 to 12 ng; direct intake from drinking water is probably much less than 1 ug/day(2). FOOD: (assume <0.1 to="" 84="" ug/kg)(4)="" >0.16 to="" 134="" >

[(1) Kimoto WI et al; Water Res 15: 1099-1106 (1981) (2) USEPA; Ambient Water Quality Criteria Doc: Nitrosamines p.C-14 (1980) EPA 440/5-80-064 (4) IARC; IARC Monographs on the Evaluation of Carcinogenic Risks to Humans 17: 125-76 (1978)]

² The calculated acceptable intake for NDMA is based on methods described in the ICH Guidance M7(R1) Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk

([http://wcms-internet.fda.gov/files/drugs/published/M7-R1-](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)

[AssessmentAndControlOfDNA-Reactive-Mutagenic-](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)

[ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)

([http://wcms-internet.fda.gov/files/drugs/published/M7-R1-](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)

[AssessmentAndControlOfDNA-Reactive-Mutagenic-](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)

[ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf](http://wcms-internet.fda.gov/files/drugs/published/M7-R1-AssessmentAndControlOfDNA-Reactive-Mutagenic-ImpuritiesInPharmaceuticalsToLimitPotentialCarcinogenicRisk-Guidance.pdf)))


7/24/2018: UPDATE - FDA publishes a list of valsartan-containing products not part of the recall

Update [7/24/2018] FDA is updating health care professionals and consumers on the agency's progress in responding to the ongoing recalls of valsartan, which is used to treat high blood pressure and heart failure, due to the presence of NDMA. The agency has posted a [list of valsartan-containing products not impacted \(/media/118232/download\)](/media/118232/download) by this recall. **FDA continues to evaluate valsartan-containing products** and will update the [list of products included in the recall \(/media/118231/download\)](/media/118231/download) and the [list of products not included in the recall \(/media/118232/download\)](/media/118232/download) as more information becomes available.

Manufacturers of these products often produce multiple dosage strengths, however not all of them are being recalled. FDA recommends health care professionals and patients carefully check these lists. Health care professionals and patients should check this statement frequently for any updates.

FDA reminds consumers to continue taking your current medicine until your doctor or pharmacist gives you a replacement or a different treatment option. Untreated hypertension (high blood pressure) leads to an increase in the risk of heart attacks and stroke. Untreated heart failure increases the risk of hospitalization and death.

Consumers and health care professionals should continue to report any adverse reactions with valsartan-containing products, to the FDA's MedWatch program (/medwatch-fda-safety-information-and-adverse-event-reporting-program) to help the agency better understand the scope of the problem:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).
- Download and complete the appropriate form, then submit it via fax at 1-800-FDA-0178 

7/18/2018: STATEMENT - FDA updates health care professionals and patients on recent valsartan recalls

[7/18/2018] The U.S. Food and Drug Administration is updating health care professionals and consumers following a recent FDA press release (/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity) about voluntary recalls of several drug products containing the active pharmaceutical ingredient (API) valsartan. Valsartan is used to treat high blood pressure and heart failure. Not all products containing valsartan are being recalled, and this update will clarify which valsartan-containing products are being recalled.

The recalled products contain an impurity, N-nitrosodimethylamine (NDMA), in the API manufactured by Zhejiang Huahai Pharmaceuticals, Linhai, China. The presence of the potentially cancer-causing NDMA was unexpected, and the agency believes the NDMA is related to changes in the way the active substance was manufactured. Some levels of the impurity may have been in the valsartan-containing products for as long as four years.

The investigation into valsartan-containing products is ongoing, and the following list may change. We will update this statement as we have more information.

There are currently three voluntary recalls related to the NDMA impurity detected in the valsartan API:

- **Teva Pharmaceuticals USA labeled as Major Pharmaceuticals** — recall is at the **retail level** because these products are only used in facilities where they are directly administered to patients by health care professionals: Valsartan 80 mg and 160 mg products;

- **Princeton Pharmaceuticals Inc. labeled as Solco Healthcare LLC** — recall is at the **consumer/user level**: Valsartan 40 mg, 80 mg, 160 mg, and 320 mg; and valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg products; and
- **Teva Pharmaceuticals labeled as Actavis LLC** — recall is at the **consumer/user level**: Valsartan 40 mg, 80 mg, 160 mg, and 320 mg; and valsartan/HCTZ 80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg, and 320 mg/25 mg products.

Detailed list of products included in the recall (/media/118231/download). (PDF - 87 KB)

What should patients know:

- Continue taking your current medicine until your doctor or pharmacist gives you a replacement or a different treatment option.
- Not all valsartan-containing medications are affected and being recalled.
- If you are taking any medication containing valsartan, compare the information on your prescription bottle with the information in this list (/about-fda/page-not-found) (company, National Drug Code, lot number) to determine if your current medicine has been recalled. If you are not certain, contact your pharmacist.
- If you have medicine included in the recall, contact your pharmacist. The pharmacist may be able to provide you with valsartan made by another company. If not, contact your doctor immediately to discuss other treatment options.

What health care professionals should know:

- FDA has determined the recalled valsartan products pose an unnecessary risk to patients. Therefore, FDA recommends patients use valsartan-containing medicines made by other companies or consider other available treatment options for the patient's medical condition.
- If you have medication samples from these companies, quarantine the products and do not provide them to patients.

Consumers and health care professionals should report any adverse reactions with valsartan-containing products, to the FDA's MedWatch program (<https://www.fda.gov/safety/medwatch/>) to help the agency better understand the scope of the problem:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>).

- Download and complete the appropriate form, then submit it via fax at 1-800-FDA-0178.

7/13/2018: PRESS RELEASE - FDA announces voluntary recall of several medicines containing valsartan following detection of an impurity

Go to [Press Release \(/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity\)](/news-events/press-announcements/fda-announces-voluntary-recall-several-medicines-containing-valsartan-following-detection-impurity).

FDA-published testing methods to provide options for regulators and industry to detect NDMA and NDEA impurities

The links below are to FDA-published testing methods to provide options for regulators and industry to detect nitrosamine impurities in ARB drug substances and drug products. These methods should be validated by the user if the resulting data are used to support a required quality assessment of the API or drug product, or if the results are used in a regulatory submission.

- [Combined headspace method \(/media/117843/download\)](/media/117843/download): a GC/MS method that allows determination of both N-Nitrosodimethylamine (NDMA) and N-Nitrosodiethylamine (NDEA) simultaneously
- [Combined direct injection method \(/media/117807/download\)](/media/117807/download): a GC-MS/MS method that allows for determination of both NDMA and NDEA simultaneously
- [Direct injection GC-MS method \(/media/123409/download\)](/media/123409/download): a method that can detect NDMA, NDEA, N-Nitrosodiisopropylamine (NDIPA), N-Nitrosoethylisopropylamine (NEIPA), and N-nitrosodibutylamine (NDBA)
- [Headspace GC-MS method \(/media/124025/download\)](/media/124025/download): a method that can detect NDMA, NDEA, NDIPA, and NEIPA
- [LC-HRMS method \(/media/125478/download\)](/media/125478/download): a method that can detect NDMA, NDEA, NEIPA, NDIPA, NDBA, and N-Nitroso-N-methyl-4-aminobutyric acid (NMBA)
- [RapidFire-MS/MS method \(/media/125477/download\)](/media/125477/download): a method that can detect NEIPA, NDIPA, NDBA, and NMBA. We do not recommend using this method to detect NDMA or NDEA because it is less sensitive to those impurities.

The LC-HRMS and RapidFire-MS/MS methods are the first methods FDA has posted for detecting NMBA. The European Directorate for the Quality of Medicines (EDQM) has also published [methods to detect NDMA and NDEA \(https://www.edqm.eu/en/ad-hoc-](https://www.edqm.eu/en/ad-hoc-)

projects-omcl-network). [↗ \(http://www.fda.gov/about-fda/website-policies/website-disclaimer\)](http://www.fda.gov/about-fda/website-policies/website-disclaimer). FDA has not validated EDQM's methods.

Resources for You

- [Search ARBs Recalls List \(/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan\)](/drugs/drug-safety-and-availability/search-list-recalled-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan)
- [Recalls of ARBs including Valsartan, Losartan and Irbesartan \(/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan\)](/drugs/drug-safety-and-availability/recalls-angiotensin-ii-receptor-blockers-arbs-including-valsartan-losartan-and-irbesartan)
- [Nitrosamine Impurities in Medications \(/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications\)](/drugs/drug-safety-and-availability/information-about-nitrosamine-impurities-medications)

Exhibit 32

N-Nitrosodimethylamine

CASRN 62-75-9 | DTXSID7021029

- [IRIS Summary \(PDF\)](#). (11 pp, 105 K)

[Key IRIS Values](#) | [Other EPA Information](#)

Noncancer Assessment

[Reference Dose for Oral Exposure \(RfD\) \(PDF\)](#). (11 pp, 105 K)
Not assessed under the IRIS Program. Last Updated:

[Reference Concentration for Inhalation Exposure \(RfC\) \(PDF\)](#).
(11 pp, 105 K)
Not assessed under the IRIS Program.

Cancer Assessment

[Weight of Evidence for Cancer \(PDF\)](#). (11 pp, 105 K)
Last Updated: 01/31/1987

WOE Characterization	Framework for WOE Characterization
B2 (Probable human carcinogen - based on sufficient evidence of carcinogenicity in animals)	Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1986)

Basis:

- Induction of tumors at multiple sites in both rodents and nonrodent mammals exposed by various routes.
- This may be a synopsis of the full weight-of-evidence narrative.

Quantitative Estimate of Carcinogenic Risk from Oral Exposure (PDF) (11 pp, 105 K)

Oral Slope Factor: 5.1×10^1 per mg/kg-day

Drinking Water Unit Risk: 1.4×10^{-3} per $\mu\text{g/L}$

Extrapolation Method: Weibull, extra risk

Tumor site(s): Hepatic

Tumor type(s): Liver tumors (Peto et al., 1984)

Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure (PDF) (11 pp, 105 K)

Inhalation Unit Risk: 1.4×10^{-2} per $\mu\text{g/m}^3$

Extrapolation Method: Weibull, extra risk

Tumor site(s): Hepatic

Tumor type(s): Liver tumors (Peto et al., 1984)

You will need Adobe Reader to view some of the files on this page. See [EPA's PDF page](#) to learn more.

[Contact Us](#) to ask a question, provide feedback or report a problem.

Related Links

- [EPA Chemicals Dashboard - N-Nitrosodimethylamine](#)
- [eChemPortal - Nitrosodimethylamine](#)

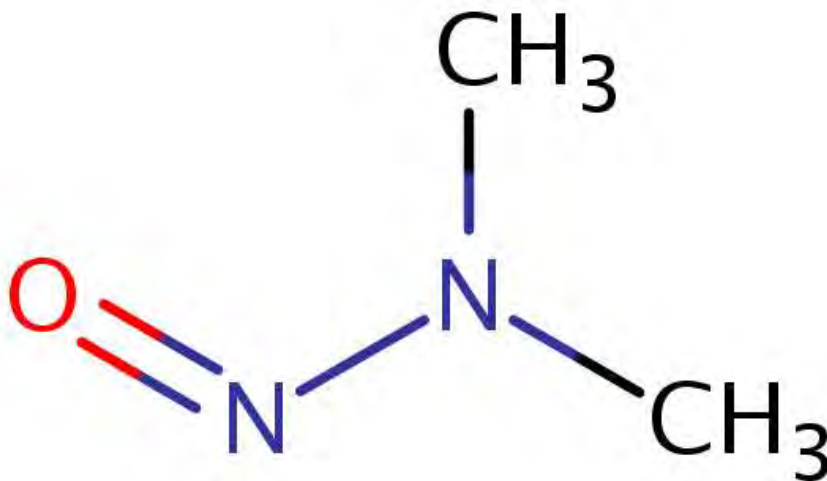
Tumor Sites



Hepatic

Chemical Structure for

N-Nitrosodimethylamine



Synonyms

- Dimethylamine, n-nitroso
- Dimethylnitrosamin
- Dimethylnitrosamine
- Dmna: dmn
- Methylamine, n-nitrosodi-

[more synonyms](#)

LAST UPDATED ON {MONTH DAY, YYYY}

Exhibit 33

N-Nitrosodiethylamine

CASRN 55-18-5 | DTXSID2021028

- [IRIS Summary \(PDF\)](#). (11 pp, 106 K)

[Key IRIS
Values](#)

[Other EPA
Information](#)

Noncancer Assessment

[Reference Dose for Oral Exposure \(RfD\) \(PDF\)](#). (11 pp, 106 K)

Not assessed under the IRIS Program.

Last Updated:

[Reference Concentration for Inhalation Exposure \(RfC\) \(PDF\)](#).

(11 pp, 106 K)

Not assessed under the IRIS Program.

Cancer Assessment

[Weight of Evidence for Cancer \(PDF\)](#). (11 pp, 106 K)

Last Updated: 01/31/1987

WOE Characterization	Framework for WOE Characterization
B2 (Probable human carcinogen - based on sufficient evidence of carcinogenicity in animals)	Guidelines for Carcinogen Risk Assessment (U.S. EPA, 1986)

Basis:

- Induction of tumors at multiple sites in both rodent and nonrodent species exposed by various routes.
- This may be a synopsis of the full weight-of-evidence narrative.

Quantitative Estimate of Carcinogenic Risk from Oral Exposure (PDF) (11 pp, 106 K)

Oral Slope Factor: 1.5×10^2 per mg/kg-day
Drinking Water Unit Risk: 4.3×10^{-3} per $\mu\text{g/L}$
Extrapolation Method: Weibull, extra risk
Tumor site(s): Hepatic
Tumor type(s): Liver tumors (Peto et al., 1984)

Quantitative Estimate of Carcinogenic Risk from Inhalation Exposure (PDF) (11 pp, 106 K)

Inhalation Unit Risk: 4.3×10^{-2} per $\mu\text{g/m}^3$
Extrapolation Method: Weibull, extra risk
Tumor site(s): Hepatic
Tumor type(s): Liver tumors (Peto et al., 1984)

You will need Adobe Reader to view some of the files on this page. See [EPA's PDF page](#) to learn more.

[Contact Us](#) to ask a question, provide feedback or report a problem.

Related Links

- [EPA Chemicals Dashboard - N-Nitrosodiethylamine](#)
- [eChemPortal - Nitrosodiethylamine](#)

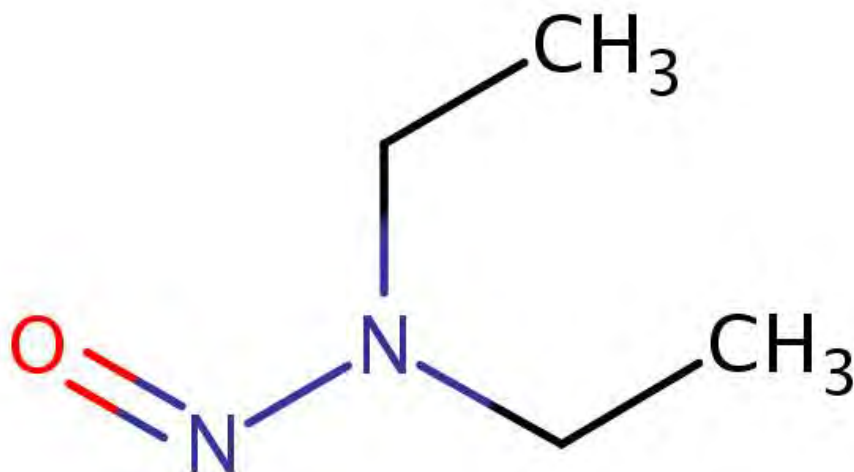
Tumor Sites



Hepatic

Chemical Structure for

N-Nitrosodiethylamine



Synonyms

- Dana: den
- Dena
- Diaethylnitrosamin
- Diethylamine, n-nitroso
- Diethylnitrosamine

[more synonyms](#)

LAST UPDATED ON {MONTH DAY, YYYY}

Exhibit 34

Welcome



Empowering a healthy tomorrow

SUMMARY, HIGHLIGHTS and TIMELINE of GENERAL CHAPTER <1469> NITROSAMINE IMPURITIES

By: Edmond Biba
Senior Scientific Liaison,
Science – General Chapters

Webinar
July 28, 2020



Background

Introduction



- ▶ Nitrosamines are common chemicals in water and foods including cured and grilled meats, dairy products and vegetables. Everyone is exposed to some level of nitrosamines.
- ▶ However, their presence in medicines, even at trace level is considered unacceptable because Nitrosamine impurities are probable human carcinogens.
- ▶ They are part of a group of high potency mutagenic carcinogens referred to as the “cohort of concern” in ICH M7. This “cohort of concern” comprises aflatoxin-like, N-nitroso- (functional group of nitrosamines), and alkyl-azoxy compounds

Exhibit 38

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,
AND IRBESARTAN PRODUCTS
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,
District Court Judge

This Document Relates to All Actions

STIPULATION OF ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD.

Pursuant to Special Master Report and Order No. 56, in exchange for Plaintiffs' agreement not to further examine a witness at deposition regarding the statements identified herein, Defendant Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP") hereby stipulates as follows:

1. ZHP states that there are no health benefits associated with the presence of NDMA or NDEA in valsartan.
2. ZHP states that the publication *Purification of Laboratory Chemicals* (4th ed.) by W.L.F. Armarego and D.D. Perrin, which was first published in 1996 and documented scientific knowledge at that time, states on page 192 that DMF

“[d]ecomposes slightly at its normal boiling point to give small amounts of dimethylamine and carbon monoxide.”

3. ZHP states that it was required to perform a risk assessment in connection with the process change to the zinc chloride process. ZHP further states the following:
 - a. ZHP states that the scientific research relied on to use DMF as part of the zinc chloride process did not include scientific research into the potential decomposition products of DMF under the conditions of the zinc chloride process.
 - b. The risk assessment of DMF did not specifically evaluate whether DMF was degrading to yield dimethylamine as part of the zinc chloride process.
 - c. Therefore, there is no document from Shanghai SynCores or ZHP that documents that potential degradation of DMF as part of the zinc chloride process was evaluated as part of the risk assessment for the zinc chloride process.
 - d. ZHP states that it did not perform a risk assessment on the potential degradation of DMF because it did not realize that DMF would degrade in the way it ultimately degraded in the zinc chloride manufacturing process of valsartan. ZHP is not saying that it was not possible to know that DMF could degrade.
 - e. ZHP never identified the nitrosamine impurities in connection with its 2011 Risk Assessment and therefore did not evaluate the nitrosamine impurities as part of any steps of the risk assessment process.

4. With regard to the Change Request Form identified as Exhibit 195 to the March 28/29, 2021 deposition of Peng Dong (copy of Exhibit attached hereto as Exhibit 1), ZHP states the following:

- a. The “Explanation Section” in Section 2 of the Change Request form on the page bearing Bates number ZHP01843067 provides a summary of the explanation for why the process change from the triethylamine hydrochloride process to the zinc chloride process was undertaken.
- b. One of the reasons for the quality review described in Section 3 of the Change Request Form on the page bearing Bates number ZHP01843069 was to identify impurities due to the new process.
- c. Section 3 of the Change Request Form on the page bearing Bates number ZHP01843070 provided that if this change was against cGMP code, it was supposed to be rejected.

Dated: May 13, 2022	<u>/s/ Richard T. Bernardo</u> Richard T. Bernardo SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP One Manhattan West New York, NY 10001-8602 richard.bernardo@skadden.com Jessica D. Miller SKADDEN, ARPS, SLATE, MEAGHER & FLOM LLP 1440 New York Avenue, N.W. Washington, D.C. 20005 jessica.miller@skadden.com Counsel for Defendant
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Exhibit 39

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE DISTRICT OF NEW JERSEY
3 CAMDEN VICINAGE

4 -----
5 IN RE: VALSARTAN, MDL NO. 2875
6 LOSARTAN, AND
7 IRBESARTAN PRODUCTS CIVIL ACTION NO.
8 LIABILITY LITIGATION 19-2875
9 (RBK/JS)

10 -----
11 THIS DOCUMENT APPLIES HONORABLE
12 TO ALL CASES ROBERT B. KUGLER

13 -----
14 - CONFIDENTIAL INFORMATION -
15 SUBJECT TO PROTECTIVE ORDER

16
17 REMOTE VIDEOTAPED EXPERT DEPOSITION OF
18 FENGtian XUE, PHD
19 Friday, February 3, 2023
20 10:04 a.m. Eastern Time

21
22 Stenographically Reported by:
23 Denise Dobner Vickery, CRR, RMR,
24 Court Reporter, Notary Public JOB NO.: 329090

<p style="text-align: right;">Page 2</p> <p>1 REMOTE APPEARANCES VIA ZOOM:</p> <p>2</p> <p>3 Representing the Plaintiffs:</p> <p>4 MAZIE SLATER KATZ & FREEMAN, LLC</p> <p>5 BY: ADAM M. SLATER, ESQ.</p> <p>6 BY: CHRISTOPHER J. GEDDIS, ESQ.</p> <p>7 103 Eisenhower Parkway</p> <p>8 Roseland, NJ 07068</p> <p>9 973.228.9898</p> <p>10 aslater@mazieslater.com</p> <p>11 cgeddis@mazieslater.com</p> <p>12</p> <p>13 Representing the Plaintiffs:</p> <p>14 MEYER WILSON CO., LPA</p> <p>15 BY: LAYNE HILTON, ESQ.</p> <p>16 900 Camp Street, Suite 337</p> <p>17 New Orleans, LA 70130</p> <p>18 614.255.2697</p> <p>19 lhilton@meyerwilson.com</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 4</p> <p>1 REMOTE APPEARANCES VIA ZOOM: (Cont'd.)</p> <p>2</p> <p>3 Representing the Defendants Zhejiang Huahai</p> <p>4 Pharmaceutical Co., Ltd., Prinston Pharmaceutical</p> <p>5 Inc., Huahai U.S., Inc., and Solco Healthcare US,</p> <p>6 LLC:</p> <p>7 SKADDEN ARPS SLATE MEAGHER & FLOM LLP</p> <p>8 BY: RICHARD BERNARDO, ESQ.</p> <p>9 BY: JOSHUA SCHOCH, ESQ.</p> <p>10 One Manhattan West</p> <p>11 New York, NY 10001</p> <p>12 212.735.2994</p> <p>13 Richard.Bernardo@skadden.com</p> <p>14 Joshua.Schoch@skadden.com</p> <p>15</p> <p>16 For Defendants Teva Pharmaceutical Industries,</p> <p>17 Ltd., Teva Pharmaceuticals USA, Inc., Actavis</p> <p>18 LLC, and Actavis Pharma, Inc.:</p> <p>19 GREENBERG TRAURIG LLP</p> <p>20 BY: BRIAN RUBENSTEIN, ESQ.</p> <p>21 1717 Arch Street, Suite 400</p> <p>22 Philadelphia, PA 19103</p> <p>23 215.988.7864</p> <p>24 rubensteinb@gtlaw.com</p>
<p style="text-align: right;">Page 3</p> <p>1 REMOTE APPEARANCES VIA ZOOM: (Cont'd.)</p> <p>2</p> <p>3 Representing the Plaintiffs:</p> <p>4 RIVERO MESTRE LLP</p> <p>5 BY: ZALMAN KASS, ESQ.</p> <p>6 BY: JORGE A. MESTRE, ESQ.</p> <p>7 2525 Ponce de Leon Boulevard, Suite 1000</p> <p>8 Miami, FL 33134</p> <p>9 786.746.8213</p> <p>10 zkass@riveromestre.com</p> <p>11 jmestre@riveromestre.com</p> <p>12</p> <p>13</p> <p>14 Representing the Plaintiffs:</p> <p>15 MARTIN HARDING & MAZZOTTI LLP</p> <p>16 BY: ROSEMARIE RIDDELL BOGDAN, ESQ.</p> <p>17 1 Wall Street</p> <p>18 Albany, NY 12205</p> <p>19 518.724.2207</p> <p>20 Rosemarie.Bogdan@1800LAW1010.com</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 5</p> <p>1 REMOTE APPEARANCES VIA ZOOM: (Cont'd.)</p> <p>2</p> <p>3 Representing the Defendant Sciegen</p> <p>4 Pharmaceutical:</p> <p>5 HINSHAW & CULBERTSON LLP</p> <p>6 BY: GEOFFREY M. COAN, ESQ.</p> <p>7 53 State Street, 27th Floor</p> <p>8 Boston, MA 02109</p> <p>9 617.213.7045</p> <p>10 GCoan@hinshawlaw.com</p> <p>11</p> <p>12 Representing the Defendant Humana:</p> <p>13 FALKENBERG IVES LLP</p> <p>14 BY: KRISTIN B. IVES, ESQ.</p> <p>15 230 West Monroe Street, Suite 2220</p> <p>16 Chicago, IL 60606</p> <p>17 312.566.4800</p> <p>18 Kbi@falkenbergives.com</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>

Page 6	Page 8
<p>1 REMOTE APPEARANCES VIA ZOOM: (Cont'd.)</p> <p>2</p> <p>3 Representing the Defendant Mylan Pharmaceuticals,</p> <p>4 Inc.:</p> <p>5 PIETRAGALLO GORDON ALFANO</p> <p>6 BOSICK & RASPANTI, LLP</p> <p>7 BY: FRANK H. STOY, ESQ.</p> <p>8 One Oxford Centre</p> <p>9 Pittsburgh, PA 15219</p> <p>10 412.263.1840</p> <p>11 fhs@pietragallos.com</p> <p>12</p> <p>13 Representing the Defendants Hetero Labs Limited</p> <p>14 and Hetero Drugs, Limited:</p> <p>15 HILL WALLACK LLP</p> <p>16 BY: WILLIAM P. MURTHA, JR., ESQ.</p> <p>17 2 Bridge Avenue, Suite 211</p> <p>18 Red Bank, NJ 07701</p> <p>19 732.924.8171</p> <p>20 wmurtha@hillwallack.com</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 INDEX</p> <p>2 EXAMINATION OF FENGtian XUE, PHD PAGE</p> <p>3 BY MR. SLATER 13</p> <p>4 AFTERNOON SESSION 164</p> <p>5 BY MR. BERNARDO 400</p> <p>6</p> <p>7</p> <p>8 DEPOSITION EXHIBITS</p> <p>9 NUMBER DESCRIPTION PAGE</p> <p>10 Exhibit 1 Defendants' Responses and 16</p> <p>11 Objections To Plaintiffs' Notice</p> <p>12 To Take Videotaped Deposition</p> <p>13 Exhibit 2 Expert Report of Fengtian Xue, 18</p> <p>14 Ph.D., December 22, 2022</p> <p>15 Exhibit 3 Supplemental Expert Report of 28</p> <p>16 Fengtian Xue, Ph.D.,</p> <p>17 January 30, 2023</p> <p>18 Exhibit 4 Exhibit A - Amended and 31</p> <p>19 Supplemental List of Materials</p> <p>20 Reviewed and Considered</p> <p>21 Exhibit 5 Deviation regarding unknown 55</p> <p>22 Impurity (genotoxicity) of</p> <p>23 Valsartan API (TEA process)</p> <p>24 PRINSTON00075797 - 00076099</p>
Page 7	Page 9
<p>1 Also Present Remotely Via Zoom:</p> <p>2</p> <p>3 JUDY DIAZ, Videographer</p> <p>4 JESSICA DAVIDSON MILLER, ESQ., Skadden Arps</p> <p>5 CHRISTOPHER HENRY, Mazie Slater</p> <p>6</p> <p>7</p> <p>8</p> <p>9</p> <p>10</p> <p>11</p> <p>12</p> <p>13</p> <p>14</p> <p>15</p> <p>16</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p>1 NUMBER DESCRIPTION PAGE</p> <p>2 Exhibit 6 Concise International Chemical 124</p> <p>3 Assessment Document 31, WHO,</p> <p>4 Geneva, 2001; N,N-DIMETHYLFORMAMIDE</p> <p>5 Exhibit 7 Shandong Hualu-Hengsheng 145</p> <p>6 Chemical Co., Ltd.,</p> <p>7 Certain of Analysis</p> <p>8 N,N-DIMETHYLFORMAMIDE</p> <p>9 Exhibit 8 International Union of Pure and 164</p> <p>10 Applied Chemistry, DIMETHYLFORMAMIDE:</p> <p>11 PURIFICATION, TESTS FOR PURITY AND</p> <p>12 PHYSICAL PROPERTIES, 1977</p> <p>13 Exhibit 9 Guidance For Industry, Genotoxic 222</p> <p>14 and Carcinogenic Impurities in Drug</p> <p>15 Substances and Products: Recommended</p> <p>16 Approaches, Draft Guidance,</p> <p>17 HHS-FDA-CDER, December 2008</p> <p>18 Exhibit 10 Investigation regarding unknown</p> <p>19 impurity (genotoxic impurity) of</p> <p>20 Valsartan API, 2018.07.08</p> <p>21 PRINSTON0076100 - 0076124</p> <p>22 Exhibit 11 Nitrosative Dealkylation of Some 256</p> <p>23 Symmetrical Tertiary Amines</p> <p>24 Gowenlock et al.</p>

<p style="text-align: right;">Page 10</p> <p>1 NUMBER DESCRIPTION PAGE</p> <p>2 Exhibit 12 Theoretical Investigation of 280</p> <p>3 N-Nitrosodimethylamine Formation</p> <p>4 from Nitrosation of Trimethylamine</p> <p>5 Sun et al., 2010</p> <p>6 ZHP01807298 - 7308</p> <p>7 Exhibit 13 Zhejiang Jianye Chemical Co., 320</p> <p>8 Ltd. Certificate of Analysis,</p> <p>9 November 25, 2012</p> <p>10 Triethylamine Analysis</p> <p>11 Exhibit 14 Zhejiang Huahai Pharmaceutical 325</p> <p>12 Co., Ltd., 2013-11-10</p> <p>13 Potential Impurities in Valsartan</p> <p>14 HUAHAI-US00007752 - 00007923</p> <p>15 Exhibit 15 Declaration of Seth A. Goldberg 343</p> <p>16 July 27, 2017</p> <p>17 Exhibit 16 Deposition of Min Li, Ph.D. 376</p> <p>18 April 22, 2021</p> <p>19</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 12</p> <p>1 ---</p> <p>2 FENGtian XUE, PHD</p> <p>3 called for examination, and, after having been</p> <p>4 duly sworn, was examined and testified as</p> <p>5 follows:</p> <p>6 MR. BERNARDO: And I apologize</p> <p>7 for interrupting so quickly. I intended,</p> <p>8 Adam, to get this in before Jessica made</p> <p>9 a start.</p> <p>10 I just want to point out,</p> <p>11 Adam, that Dr. Xue has been recovering</p> <p>12 from COVID all week and has been powering</p> <p>13 through and is here and ready to go, as</p> <p>14 he'll tell you.</p> <p>15 I just want to ask for your</p> <p>16 patience because he may be soft-spoken at</p> <p>17 times, and I told him to try and speak up</p> <p>18 just because his voice is a little worn.</p> <p>19 And also we may have to ask for a break</p> <p>20 sooner than ordinarily, but I'm sure that</p> <p>21 won't present a problem.</p> <p>22 I just wanted to explain to</p> <p>23 you the reason for all that.</p> <p>24 MR. SLATER: Whatever it is,</p>
<p style="text-align: right;">Page 11</p> <p>1 PROCEEDINGS</p> <p>2 ---</p> <p>3 THE VIDEOGRAPHER: We are now</p> <p>4 on the record.</p> <p>5 My name is a Judy Diaz. I'm a</p> <p>6 legal videographer for Golkow Litigation</p> <p>7 Services. Today's date is February 3,</p> <p>8 2023 and the time is 10:04 a.m.</p> <p>9 This remote video deposition</p> <p>10 is being held in the matter of Valsartan,</p> <p>11 Losartan, and Irbesartan Products</p> <p>12 Liability Litigation MDL.</p> <p>13 The deponent is Fengtian Xue,</p> <p>14 PhD.</p> <p>15 All parties to this deposition</p> <p>16 are peering remotely and have agreed to</p> <p>17 the witness being sworn in remotely.</p> <p>18 All counsel will be noted on</p> <p>19 the stenographic record.</p> <p>20 The court reporter is Denise</p> <p>21 Vickery and will now swear in the</p> <p>22 witness.</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 13</p> <p>1 we're here for the duration. We are</p> <p>2 here.</p> <p>3 ---</p> <p>4 EXAMINATION</p> <p>5 ---</p> <p>6 BY MR. SLATER:</p> <p>7 Q. Hope you feel better. Hope you are</p> <p>8 feeling better, Doctor.</p> <p>9 A. Thank you.</p> <p>10 Q. Let me -- by the way, to pronounce</p> <p>11 your name tell me, the proper pronunciation</p> <p>12 please.</p> <p>13 A. Please call me Fengtian. Or you</p> <p>14 want me to --</p> <p>15 MR. BERNARDO: I think he's</p> <p>16 asking for how to pronounce your last</p> <p>17 name, Doctor.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Yes, Doctor, because I've heard it</p> <p>20 pronounced a few different ways. I want to make</p> <p>21 sure I get it right.</p> <p>22 A. What is the fast way "Xue."</p> <p>23 Q. Xue. Okay. I think I can handle</p> <p>24 that.</p>

<p style="text-align: right;">Page 14</p> <p>1 MR. SLATER: All right. 2 Great. Are we on the record now? 3 THE VIDEOGRAPHER: Yes, we're 4 on the record. 5 MR. SLATER: Okay. Great. 6 BY MR. SLATER: 7 Q. Good morning, Dr. Xue. 8 A. Good morning. 9 Q. I'm Adam Slater. We've just 10 introduced ourselves. 11 You understand we're here to take 12 your deposition, correct? 13 A. I understand. 14 Q. Have you ever had your deposition 15 taken before? 16 A. First time in my life. 17 Q. There's a few important things that 18 you should know. 19 The one that's most important to me 20 is that if you don't understand a question or it 21 doesn't make sense to you for any reason such that 22 you don't know if you can answer it truthfully or 23 accurately, just say something. You can say, "I 24 don't understand your question." Maybe you don't</p>	<p style="text-align: right;">Page 16</p> <p>1 form of the question." What he's saying is, 2 Mr. Slater, you're not answering the -- asking the 3 question properly under the rules of evidence. 4 You may still answer the question. 5 I would say in most cases you probably will. He's 6 preserving his rights. I can re-ask the question 7 differently. I can proceed with it. You 8 shouldn't be thrown off by that. 9 Just let -- if somebody objects, 10 just let us address it, and then I would think for 11 most -- and you'll get into the rhythm -- in most 12 cases you'll probably just answer the question, 13 but it's allowed. The lawyer is allowed to 14 object. So just don't -- it's not -- not 15 something you have to be concerned about, but 16 you'll hear the objections from time to time. 17 Okay? 18 A. Okay. 19 MR. SLATER: Let's first put 20 up as Exhibit 1 the deposition notice. 21 Actually, the responses and objections to 22 the deposition notice. Let's do that. 23 (Document marked for 24 identification as Xue Exhibit 1.)</p>
<p style="text-align: right;">Page 15</p> <p>1 hear it. Maybe I mispronounce a scientific term. 2 It could be for a whole host of reasons that you 3 don't feel comfortable you understand what I'm 4 asking. 5 You can just tell me that. I might 6 ask what's unclear. I might ask what the issue 7 is. You can tell me, and I'll try to work to get 8 a question out that you feel comfortable answering 9 on the subject matter I'm trying to get into. 10 Okay? 11 A. Thank you. 12 I also want to point out, I'm -- I 13 speak English for 20-plus years but still my 14 vocabulary is not the biggest. Sometimes if you 15 speak a word, I may not be able to recognize what 16 the meaning of the word. I may also point that 17 out. 18 Q. If for any reason you feel like you 19 need clarification on anything I'm asking you, I 20 want you to tell me. 21 A. Thank you. I will do. 22 Q. There may be objections during the 23 course of the deposition. Lawyers are allowed to 24 object. Mr. Bernardo can say, "Objection to the</p>	<p style="text-align: right;">Page 17</p> <p>1 MR. SLATER: Yeah, I'm -- 2 yeah, let's put it on the screen. 3 BY MR. SLATER: 4 Q. Dr. Xue, did you review the 5 deposition notice that we had served in advance of 6 the deposition? 7 A. Excuse me. Do I suppose to have 8 this file also in the folder that sent to me? 9 Q. I don't know the answer to that 10 question. 11 A. I just refreshed the folder that 12 sent. Okay. Now I can see the file. 13 Q. Okay. I'm actually not asking about 14 this document yet. It's just on the screen. I'm 15 asking a different question. 16 A. Okay. 17 Q. Did you see the deposition notice 18 that was served in this case for your deposition? 19 A. I am being seeing so many documents. 20 Q. On -- on the screen, we have 21 Exhibit 1, which is "Defendants' Responses and 22 Objections to Plaintiffs' Notice to Take 23 Videotaped Deposition." This is for -- this is 24 the response by the attorneys to our request for</p>

<p style="text-align: right;">Page 18</p> <p>1 documents in advance of the deposition.</p> <p>2 Have you seen this response?</p> <p>3 A. I -- I think so. There's -- there's</p> <p>4 multiple items that I need to address there,</p> <p>5 right, to respond to those questions.</p> <p>6 Q. Did you do that? Did you go through</p> <p>7 the various requests and -- and make sure that</p> <p>8 anything that was requested was provided to the</p> <p>9 attorneys to provide to us?</p> <p>10 A. I think I did.</p> <p>11 MR. SLATER: Okay. Great.</p> <p>12 You can take that down.</p> <p>13 Let's put up as Exhibit 2, the</p> <p>14 report, please.</p> <p>15 (Document marked for</p> <p>16 identification as Xue Exhibit 2.)</p> <p>17 BY MR. SLATER:</p> <p>18 Q. We've put up on the screen</p> <p>19 Exhibit 2, which is the report we were served</p> <p>20 dated December 22, 2022, and it was signed by you</p> <p>21 at the end on page 58.</p> <p>22 Is that the report that you wrote in</p> <p>23 this case?</p> <p>24 A. Yes. You showed me the first page.</p>	<p style="text-align: right;">Page 20</p> <p>1 and Considered."</p> <p>2 Was that a complete list of the</p> <p>3 materials that you reviewed and considered as of</p> <p>4 the time that you authored your report dated</p> <p>5 December 22, 2022?</p> <p>6 A. Yes, I did all the -- my own search.</p> <p>7 Also the material provide by the counsels. I</p> <p>8 think everything that I considered when I write</p> <p>9 this report, offer my opinion, I put in that. I</p> <p>10 think it's called a list of material.</p> <p>11 MR. SLATER: Chris, can you go</p> <p>12 to that Exhibit A, please, the first</p> <p>13 page? Perfect.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Looking at the Exhibit A to your</p> <p>16 report items 8, 9, and 10 are interviews with Min</p> <p>17 Li, Jucai Ge, and Jinsheng Lin.</p> <p>18 Do you see that?</p> <p>19 A. Yes, 8, 9, and 10 are the two --</p> <p>20 sorry -- three interviews.</p> <p>21 Q. Did you take notes of those</p> <p>22 interviews?</p> <p>23 A. I didn't take notes for neither of</p> <p>24 them.</p>
<p style="text-align: right;">Page 19</p> <p>1 By the first page, that is the report that I read.</p> <p>2 Q. And attached to the report --</p> <p>3 A. I'm sorry. I wrote, not read. I</p> <p>4 apologize.</p> <p>5 Q. Okay. Attached to the report was a</p> <p>6 curriculum vitae.</p> <p>7 Is that your up-to-date current</p> <p>8 curriculum vitae?</p> <p>9 A. Can you explain what "curriculum</p> <p>10 vitae" mean?</p> <p>11 Q. It's the list of your background,</p> <p>12 experience, your training, your education that we</p> <p>13 were provided.</p> <p>14 A. Oh. Oh.</p> <p>15 Q. It starts with your name at the top.</p> <p>16 It says that your title was associate professor,</p> <p>17 etc.</p> <p>18 A. Yeah. Sorry. I used to call it CV.</p> <p>19 You know, as I said, the word was not sound</p> <p>20 directly to me.</p> <p>21 Yes, I attach a copy of my CV to</p> <p>22 this report.</p> <p>23 Q. And then listed as Exhibit A to the</p> <p>24 report was something titled "Materials Reviewed</p>	<p style="text-align: right;">Page 21</p> <p>1 Q. Was anybody present when you</p> <p>2 interviewed those three people?</p> <p>3 A. Well, you mean besides me and the</p> <p>4 three people individual?</p> <p>5 Q. Correct.</p> <p>6 A. No, only a pair of us. Like if I</p> <p>7 interview Min Li, only Min Li and I was there.</p> <p>8 Q. Were -- were these interviews</p> <p>9 conducted in person or by some other means?</p> <p>10 A. All of them was through Internet.</p> <p>11 Q. Were you able to see each other?</p> <p>12 Was it by Zoom or something similar to Zoom?</p> <p>13 A. I didn't see them at all.</p> <p>14 Q. Were the interviews spoken or were</p> <p>15 they e-mails back and forth?</p> <p>16 A. I first reach out to them to make</p> <p>17 appointment. During the interview was just talk.</p> <p>18 Q. Do you know where each of those</p> <p>19 people were located when you interviewed them?</p> <p>20 A. Honestly, I don't know. I don't</p> <p>21 remember ask that question. I should not make</p> <p>22 speculation. I believe Jucai Ge and Dr. Jinsheng</p> <p>23 Lin was in China. Dr. Min Li might be in the U.S.</p> <p>24 Q. Had you ever met any of those people</p>

<p style="text-align: right;">Page 22</p> <p>1 before you interviewed them?</p> <p>2 A. I never met either of the three.</p> <p>3 Q. Were these interviews recorded?</p> <p>4 A. No, I didn't record any of the</p> <p>5 interviews.</p> <p>6 Q. When I went through your report, I</p> <p>7 did not see any reference to those interviews, any</p> <p>8 of the content of those interviews.</p> <p>9 Am I correct that nowhere in your</p> <p>10 report did you actually recite what those people</p> <p>11 told you during the interviews?</p> <p>12 A. Well, I talk them to them before I</p> <p>13 start writing my report. So some of the knowledge</p> <p>14 or information that I heard -- I heard from them I</p> <p>15 confirm with them my, you know, gave me idea that</p> <p>16 I -- that we think the conservation scope that I</p> <p>17 used to form my opinions.</p> <p>18 Q. In forming your opinions in this</p> <p>19 case, did you rely in part on those interviews</p> <p>20 with Min Li, Jucai Ge, and Jinsheng Lin?</p> <p>21 A. When you say "rely" means I cite</p> <p>22 them or I consider them. I just don't quite know</p> <p>23 what you really mean here.</p> <p>24 Q. In terms of the basis for the</p>	<p style="text-align: right;">Page 24</p> <p>1 something that they want me to know. As</p> <p>2 I said, I -- I consider that those when I</p> <p>3 form my opinions.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Did you speak with anybody else from</p> <p>6 ZHP or any of the companies affiliated with ZHP</p> <p>7 other than Min Li, Jucai Ge, and Jinsheng Lin with</p> <p>8 regard to this matter?</p> <p>9 A. With regard to this case, I never</p> <p>10 speak to anybody other than the three that listed</p> <p>11 here.</p> <p>12 Q. Before you were retained in this</p> <p>13 case, did you know anybody that has worked at ZHP</p> <p>14 or Princeton?</p> <p>15 A. No, I actually know nobody from</p> <p>16 those companies.</p> <p>17 Q. Do you know a toxicologist named</p> <p>18 Charles Wong?</p> <p>19 A. I have no idea because, you know,</p> <p>20 Charles Wong is a very common, you know, Chinese</p> <p>21 name.</p> <p>22 Q. I'm asking about a toxicologist</p> <p>23 named Charles Wong.</p> <p>24 A. No, I don't know any toxicologist</p>
<p style="text-align: right;">Page 23</p> <p>1 opinions you gave in your report --</p> <p>2 A. Right.</p> <p>3 Q. -- was one of the things that you</p> <p>4 relied on the interviews with Min Li, Jucai Ge,</p> <p>5 and Jinsheng Lin?</p> <p>6 MR. BERNARDO: Object to the</p> <p>7 form of the question. Vague.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. I'll ask the question again.</p> <p>10 In forming the opinions you formed</p> <p>11 in this case --</p> <p>12 A. Right.</p> <p>13 Q. -- was one of the things that you</p> <p>14 relied on the information you got from Min Li when</p> <p>15 you interviewed him?</p> <p>16 MR. BERNARDO: Object to the</p> <p>17 form of the question. Vague.</p> <p>18 THE WITNESS: As I said just</p> <p>19 now, when I interview not just Min Li,</p> <p>20 each one of the three ZHP employees, I</p> <p>21 had a conversation and they gave an</p> <p>22 introduction about what happened. I</p> <p>23 usually ask a couple questions.</p> <p>24 Yeah. They will highlight</p>	<p style="text-align: right;">Page 25</p> <p>1 named Charles Wong.</p> <p>2 Q. Is there any place in the report</p> <p>3 where you actually refer to anything that Min Li,</p> <p>4 Jucai Ge, or Jinsheng Lin told you during those</p> <p>5 interviews?</p> <p>6 I didn't see anything like that, but</p> <p>7 I'm asking if that's there and I missed it.</p> <p>8 A. I didn't cite anything that either</p> <p>9 one of the three people -- Jinsheng Lin, Jucai Ge,</p> <p>10 or Min Li -- told me.</p> <p>11 Q. There's a number of documents listed</p> <p>12 on this list of Materials Reviewed and Considered.</p> <p>13 Did you read every single one of the</p> <p>14 documents listed?</p> <p>15 A. I probably read every one. That's</p> <p>16 why it's listed here, but, you know, it has been a</p> <p>17 long journey. I've been reading so many</p> <p>18 documents, and also I did literature search on</p> <p>19 multiple reaction situations. I cannot say that I</p> <p>20 remember everything that I read and memorized</p> <p>21 because this report was written -- don't know --</p> <p>22 40 days ago. I honestly have been fairly busy</p> <p>23 and, on top of that, I've been suffer from COVID</p> <p>24 recently.</p>

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1 So I cannot say that I remember
2 everything that I -- I saw, but I'll try my best.
3 Q. Are you alone in that room that
4 you're in right now?
5 A. I am.
6 Q. Do you have any documents in hard
7 copy with you for this deposition?
8 A. Well, I have this plain report of
9 myself that you showing me in front of me. It's
10 closed. I'm not sure whether I'm allowed to read
11 it.
12 Q. Yes, you are.
13 A. Am I allowed to read my report?
14 Q. Yes.
15 A. Okay.
16 Q. I'm going to ask you at times about
17 the report, or if I ask questions and you need to
18 refer to the report, you can do so.
19 What I'm asking you right now is
20 just what documents you have. If you can just
21 list for me what you have out there.
22 A. That's the only -- only document I
23 have, other than the two screens in front of me.
24 Q. And when you say "the two screens,"

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1 one screen for the Zoom and then another screen
2 where you can electronically access documents?
3 A. Yes. So I have the screen. I see
4 you and I see everybody and see the document of
5 Exhibit A. On the other one, I have the folder.
6 It's called my name "Marked Exhibits" right now
7 showing on there.
8 MR. SLATER: You could take
9 that off the screen, Chris.
10 BY MR. SLATER:
11 Q. You said you have your report in
12 front of you. So I'm not going to need to put
13 the report up anymore. You can look at it.
14 Unless I need to show you a
15 particular thing, I can put it up, but it will
16 just be easier. You can look at it.
17 A. Yes, that's --
18 Q. You can look at something.
19 Your report sets forth various
20 opinions.
21 Are those all of the opinions that
22 you formed in this case at the time you wrote the
23 report?
24 A. So you talk about the three reports

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1 -- sorry -- three opinions on page 3?
2 Q. Those are your three opinions in
3 this case, the three bullet pointed opinions on
4 page 3?
5 A. Yes.
6 Q. You also wrote a supplemental
7 report.
8 MR. SLATER: Why don't we
9 throw that up, Chris, just to get it
10 identified.
11 Yeah, let's do as Exhibit 3
12 the supplemental report.
13 (Document marked for
14 identification as Xue Exhibit 3.)
15 BY MR. SLATER:
16 Q. Unless, Doctor, do you have that
17 handy also or do you only have your --
18 A. No. I didn't even know I'm allowed
19 to use the report. So I didn't print out the
20 supplementary. Maybe I have to --
21 Q. No problem.
22 A. -- put it up when I need it. Thank
23 you.
24 Q. Do you recognize Exhibit 3 as the

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1 supplemental report you wrote in this case dated
2 January 30, 2023?
3 A. Yes.
4 Q. It looked like this was a response
5 or a commentary on some of the testimony that was
6 given by Dr. Najafi in his deposition; is that
7 correct?
8 A. Yes, it is correct.
9 Q. Did you form any new opinions and
10 place those in that report, or did your opinions
11 as stated on page 3 of your first report remain
12 the same and did they remain as your only
13 opinions?
14 MR. BERNARDO: Object to the
15 form of the question. Vague.
16 BY MR. SLATER:
17 Q. I'll ask the question again.
18 Did you add any new opinions when
19 you wrote the supplemental report?
20 I didn't see any new opinions, but I
21 just want to make sure from your perspective you
22 didn't add any new opinions when you wrote the
23 supplemental report.
24 A. As he point out -- sorry.

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1 MR. BERNARDO: I was just
2 going to object to the form of the
3 question.
4 But you can go on, Dr. Xue.
5 THE WITNESS: As you point
6 out, this report was written recently to
7 address Dr. Najafi's deposition recent
8 happened. I'm trying to use my knowledge
9 in chemistry to address some of his
10 statements.
11 My main opinions are listed in
12 my earlier report, the main report, the
13 three points stays.
14 BY MR. SLATER:
15 Q. The three opinions set forth in your
16 initial report remain the same even when you wrote
17 the supplemental report.
18 Is that what you're telling me?
19 I just want to confirm that.
20 A. (Reviews document.)
21 Q. Let me ask the question differently.
22 A. I'm sorry. Yes, go ahead.
23 MR. BERNARDO: I think he's
24 just looking to confirm, Adam, just give

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1 him a moment.
2 BY MR. SLATER:
3 Q. Yeah.
4 A. Yeah, I just want to make sure
5 everything I said is -- is --
6 Q. Oh, I didn't realize you were
7 looking at the report to answer the question.
8 Go ahead. I'm sorry. Go ahead.
9 A. Yeah.
10 Q. And just for the record, the
11 question is: The supplemental report did not
12 change or add any new opinions; is that correct?
13 A. I'll agree there's no additional
14 point that I want to add. I just want to address
15 the -- the comments or points that Dr. Najafi
16 raised during his deposition recently.
17 MR. SLATER: And just to be
18 fair, with regard to the reliance list,
19 let's mark as Exhibit 4 the "Amended and
20 Supplemental List of Materials Reviewed
21 and Considered."
22 (Document marked for
23 identification as Xue Exhibit 4.)
24 BY MR. SLATER:

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1 Q. We'll mark this as Exhibit 4.
2 I saw that some depositions were
3 added to the list of Dr. Hecht and Dr. Najafi and
4 Dr. Plunkett.
5 To your knowledge, was anything else
6 added to this amended and supplemental list as
7 compared to the original list?
8 A. I add because these, you said those
9 three depositions happened after my original
10 report, and I reviewed them. So I want to add
11 these depositions to the material conservation.
12 Also, I also add a paper that was --
13 it's just one paper I want to add to that as well.
14 Q. Which paper was that?
15 A. I honestly don't remember exactly
16 what the paper's title was, but it -- yeah, I can
17 look through to -- to find it. Is that --
18 Q. Do you recall why you wanted to add
19 that paper? What the subject matter was?
20 A. Well, because that's just when I --
21 when I originally write the report. There's a
22 bunch of examples of reaction conditions I want to
23 support. So I did literature search. I found
24 these maybe -- I don't know -- few dozens of

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1 papers and those are one of that.
2 And I honestly don't remember what
3 was the reason, but I just put on -- I run
4 literature and I recognize later on, and then I
5 decide to just give the counsel that additional
6 paper.
7 Q. We also received an e-mail
8 yesterday, February 2nd, that indicated that when
9 you were preparing for this deposition, you
10 noticed that a few of the deposition transcripts
11 you reviewed were inadvertently omitted from the
12 list of materials considered, including Jucai Ge
13 deposition May 26 and May 27, 2022 and Pang Dong
14 deposition April 1, 2021.
15 Is that correct that you also had
16 read those depositions?
17 A. Oh, I did.
18 Q. Did you read the deposition
19 transcripts complete from cover to cover?
20 A. I honestly won't say that. Because
21 especially Jucai Ge's it's very long. I won't say
22 I read line to line every line, but I cover most
23 of part when I prepared for my -- for my report.
24 For -- for Dong -- I forgot his

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1 first name -- that deposition I only read a small
 2 portion. Because that I remember was I asked for
 3 this deposition because Dr. Najafi or maybe
 4 Dr. Hecht -- I forgot -- during their deposition,
 5 they use this as their additional, one of the
 6 papers, 2010, some -- some therapeutic studies --
 7 sorry -- theoretical calculations where that paper
 8 came to me as part of Pang Dong's deposition, and
 9 that's why I ask for the counsel to sent me his
 10 deposition to look.
 11 But I didn't look Pang Dong's for
 12 the most part.
 13 MR. SLATER: We can take down
 14 that reliance list.
 15 BY MR. SLATER:
 16 Q. I want to ask you a couple questions
 17 about your report again, the initial report,
 18 December 22, 2022, Exhibit 2.
 19 A. Yes.
 20 Q. The report lists a lot of facts,
 21 some in great detail, a lot of information.
 22 Would that be information that you
 23 felt was most important to you in forming your
 24 opinions in this case? Is that why that

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1 information is what you actually discussed in the
 2 report?
 3 A. When I write report or any art --
 4 scientific papers I wrote in my career, I always
 5 trying to present my opinion or my discovery in a
 6 way that I highlighting the case. I use some
 7 avenues to support my -- my -- my point. If I
 8 have opinion overall in scientific writing we call
 9 it conclusions, I usually also highlight that in
 10 the writing. So that's just my style.
 11 I -- I guess I hope that answer your
 12 question.
 13 Q. My question is: The facts that you
 14 discussed in your report.
 15 A. Right.
 16 Q. Are those the facts that were most
 17 important to you in forming your opinions?
 18 MR. BERNARDO: Object to the
 19 form of the question. Vague.
 20 THE WITNESS: Well, I can only
 21 say that these are the fact that I, you
 22 know, I read. When I write this report,
 23 I mostly read the plaintiffs' experts'
 24 report from, I think, four experts, and

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1 then I see their points and then I try to
 2 address their points in a way that my
 3 understanding of the science behind the
 4 case. Like the nitrosamines, NDMA's,
 5 NDEAs, these process. That's what I --
 6 what I did.
 7 I cannot really see that I
 8 highlight everything. Mostly we need to
 9 focus on what the experts on the
 10 plaintiff side talked about.
 11 BY MR. SLATER:
 12 Q. You prepared for this deposition,
 13 right?
 14 Did you prepare for this deposition?
 15 Did you prepare yourself?
 16 A. I did. You see what (indicates).
 17 Q. Okay. Is one of the things you did
 18 in preparing for the deposition reading your
 19 report?
 20 MR. BERNARDO: Object to the
 21 form of the question. Vague.
 22 THE WITNESS: Well, I don't --
 23 BY MR. SLATER:
 24 Q. Dr. Xue, it's a very simple

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1 question.
 2 A. I know.
 3 Q. Did you read your report as part of
 4 your preparation for today's deposition?
 5 MR. BERNARDO: Object to the
 6 form of the question. Argumentative.
 7 Go on, Dr. Xue.
 8 THE WITNESS: I wrote my
 9 report. I read my report.
 10 BY MR. SLATER:
 11 Q. So the answer is yes?
 12 MR. BERNARDO: Object to the
 13 form of the question. Vague.
 14 Adam, why don't you ask him
 15 the question. From what he demonstrated
 16 with his attire, I think it's clear he
 17 didn't understand what you meant by
 18 prepared.
 19 He's trying to be very
 20 responsive as I can tell, but I think he
 21 pointed out at the very beginning of this
 22 deposition some language issues. So if
 23 you could just re-ask the question, I
 24 think he didn't understand it.

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1 MR. SLATER: Okay.

2 BY MR. SLATER:

3 Q. Dr. Xue.

4 A. Yes.

5 Q. Did you review documents, including

6 your report, in order to prepare yourself to

7 answer questions today during the deposition?

8 A. Oh, yeah, I did read my report.

9 Q. That's all I asked.

10 A. Okay. Thank you. I -- yeah.

11 Q. When you read the report in

12 preparation for the deposition, did you think to

13 yourself that there were any important facts that

14 you're relying on that were not discussed in the

15 report?

16 A. I read my report. I honestly never

17 ask myself that question. I review all my core

18 key opinions stay because I -- this is not

19 something come to me simply, right? So I know

20 this is important case. I did my study. I formed

21 them, these -- these -- these opinions.

22 Yeah. I definitely read my report

23 before the deposition, but I -- I don't think I,

24 you know, I will question myself. This is

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1 something I seriously prepared.

2 Q. Are there any facts that are

3 important to you that you're relying on to support

4 the opinions you gave that are not in your report,

5 that are not discussed in the report? Anything

6 you can point to?

7 The answer may be nothing. I just

8 want to know if there's anything outside the

9 report factually that you're relying on that's not

10 discussed in the report that you can tell me right

11 now.

12 It's a yes-or-no question.

13 A. Can I get a confirmation? Are you

14 asking whether every single point that I rely on

15 to form this report is covered or listed in my

16 report? Is that your question?

17 Q. My question is: Are there any facts

18 that are important to you in forming your

19 opinions?

20 A. Right.

21 Q. Facts that you're relying on to say,

22 "This is my opinion. It's based on this." Where

23 you would say, "I didn't talk about that fact in

24 my report."

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1 Is there anything like that?

2 MR. BERNARDO: Object to the

3 form of the question. Vague. Broad.

4 THE WITNESS: I honestly -- I

5 cannot answer this question with a yes or

6 no. Because, you know, writing papers or

7 writing reports is, it's everything come

8 to me. I read. I digest the opinions

9 from the experts on -- on the plaintiff

10 side. Excuse me.

11 And then I do my own little

12 search. I digest the case. Understand

13 each piece, what the science told me, and

14 then I form my own.

15 Like as you just read, there

16 are three key things. I don't know

17 whether I can say every single fact was

18 addressed or shown in the -- in my

19 report. Yeah.

20 I hope that answer your

21 question.

22 BY MR. SLATER:

23 Q. When I read your report, both your

24 reports, I did not see any criticisms by you of

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1 ZHP.

2 Are there any opinions that you have

3 in any of your reports where you criticize

4 anything ZHP did?

5 A. Well, I -- I just -- I think I

6 explain this just now, right? So I --

7 Q. It's a yes-or-no question, Doctor.

8 Let me ask it again because I think you're -- I

9 don't know what you're -- you may not have been

10 deposed before, but if you're going to give me

11 long stories in response to questions that are

12 simple yes or noes, we're going to go much longer

13 than necessary.

14 So let me try it again with you.

15 MR. BERNARDO: Objection.

16 BY MR. SLATER:

17 Q. Make it a smaller question for you.

18 Are there any criticisms of ZHP in

19 either of your reports?

20 A. I really tried my best to help. I'm

21 not trying to not answer short, right? But these

22 questions are not to me yes or no questions.

23 Q. All right. Well, then, let me ask

24 it again so that I try to get it to a yes or no.

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1 Do you have any opinions critical of
2 ZHP where you're saying ZHP did something wrong or
3 failed to do something it should have done?
4 A. I'm -- I was retained by the ZHP
5 counsel to offer my opinion to address the
6 plaintiffs' experts' point and since during I read
7 all these report from the plaintiffs' experts.
8 They were saying everything ZHP did was wrong,
9 right? So I was trying to address that.
10 So I really don't feel that I -- I
11 have any, you know, when I approach this, come up
12 with the report, I don't have any intention to do
13 so.
14 Q. No intention to criticize ZHP in any
15 way? Is that what you mean when you said --
16 listen, let me ask it again.
17 When you said, "I had no intention
18 to do so," did you -- were you saying you had no
19 intention to criticize ZHP? Is that what you
20 meant when you said "to do so," yes or no?
21 A. Well, I probably didn't make myself
22 clear. If that's my language issue, I already
23 said I feel sorry about that. But I tried to
24 explain, right?

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1 So I'm here as a -- as an expert in
2 organic chemistry trying to address the experts on
3 the plaintiff side points and then that's how, you
4 know, I form my report around that theme.
5 So I'm -- in other words, I'm really
6 -- I don't -- I'm not here to criticize anybody.
7 I just want to address the point that the
8 plaintiffs' expert offered.
9 I hope that answer your question.
10 Q. It does and it's helpful because it
11 was something I was going to get into in a few
12 minutes. So you brought me there so we can go
13 there now.
14 I think what you're -- what you're
15 telling me is that you -- rephrase.
16 I think what you're telling me is
17 you understood your role in this case to respond
18 to the plaintiff expert reports in the field of
19 organic chemistry; is that correct?
20 A. I disagree.
21 Q. Okay. Let me ask a different
22 question then.
23 What is your understanding of what
24 your role was as an expert in this case?

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1 You just told me you were responding
2 to the plaintiffs' experts.
3 Was there anything else that you
4 thought was your role in this case?
5 A. My role is, I was retained by the
6 ZHP counsel as an expert in organic chemistry to
7 offer my own opinion about this whole case, and I
8 was also given or, you know, provided the
9 material, including the major material was the
10 four report from the plaintiffs' experts. Of
11 course, they have a lot of citation in there as
12 well.
13 Yeah. So that's the scope of my --
14 my role here I thought because I'm an organic
15 chemist. I might offer some expertise in my area.
16 I try to understand the whole case throughout
17 reading all the -- all the informations available
18 to me, and I did my own search as well to see what
19 the science was about at that time when they
20 actually developed these processes, all these
21 things. And then I come up with a report.
22 That's my understanding about --
23 sorry -- my role here.
24 Q. Did you form any opinions during

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1 your work as an expert in this case where the
2 opinion is that ZHP either did something that it
3 should not have done or failed to do something
4 that it should have done?
5 A. Well --
6 Q. Actually, let me ask the question
7 differently.
8 As you sit here now --
9 A. Right.
10 Q. -- as an expert, do you have any
11 criticisms of ZHP?
12 MR. BERNARDO: Object to the
13 form of the question. Asked and
14 answered.
15 BY MR. SLATER:
16 Q. You can answer, Doctor.
17 Do you have any opinions critical of
18 ZHP?
19 MR. BERNARDO: Object to the
20 form of the question. Vague.
21 THE WITNESS: I really don't
22 want to repeat myself but --
23 BY MR. SLATER:
24 Q. It's a yes-or-no question, Doctor.

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1 A. As I said, I really tried if I can
2 answer yes or no, that would be easy. I really
3 cannot because this is, like I mention that I was
4 retained as organic chemist to offer my opinion
5 about the case. I offered all these effort report
6 from the experts from the plaintiff side. I read
7 them. I digest them. I do my own search.
8 Yeah. So I -- these three, as you
9 just read the three, are my -- my -- my opinions.
10 That's -- that I think is clear.
11 Q. Yeah. I'm asking you now.
12 A. Okay.
13 Q. As you sit here now.
14 A. Right.
15 Q. Do you have the opinion that ZHP did
16 anything wrong?
17 A. Okay. So --
18 MR. BERNARDO: Wait. Wait.
19 Object to the form of the
20 question. And, Adam, he's trying to
21 respond. I think the scope of his
22 opinions are clearly delineated. He's
23 trying to explain that in his report.
24 He's here to offer an opinion

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1 about organic chemistry, not company
2 conduct. He's tried to answer your
3 question. This sort of goes back to the
4 hearing I recall with Judge Vanaskie
5 saying, you know, you can ask it several
6 times and then move on. So I object --
7 MR. SLATER: Rich. Rich.
8 MR. BERNARDO: I object --
9 MR. SLATER: Don't talk with
10 me right now, please. That's -- you're
11 totally out of line.
12 MR. BERNARDO: I object to
13 this continued line of questions. Go on.
14 MR. SLATER: That's okay. I
15 have a witness who's having a hard time
16 even understanding or responding to my
17 questions, and you're giving me a hard
18 time about following up?
19 MR. BERNARDO: I think the
20 witness --
21 MR. SLATER: I'm taking the
22 deposition now, okay? If you want to put
23 it in that context, then we'll -- then
24 we'll get much more direct.

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1 BY MR. SLATER:
2 Q. Doctor --
3 MR. BERNARDO: I'm simply
4 preserving my objection.
5 MR. SLATER: That's okay. I'm
6 going to ask a question.
7 BY MR. SLATER:
8 Q. Doctor, as an expert in this case,
9 did you consider whether or not ZHP failed to do
10 anything in connection with the development of the
11 manufacturing processes at issue in this case?
12 Did you think --
13 MR. BERNARDO: Object.
14 BY MR. SLATER:
15 Q. -- about that whether or not ZHP
16 failed to do anything it should have done?
17 MR. BERNARDO: Object to the
18 form of the question. Vague. Overly
19 broad. Asked and answered.
20 You can answer, Dr. Xue.
21 BY MR. SLATER:
22 Q. All right. You can answer.
23 A. I'll try one last time. I really --
24 Q. It's a yes-or-no question, Doctor.

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1 MR. BERNARDO: Adam, please
2 don't interrupt him --
3 THE WITNESS: As I said --
4 MR. BERNARDO: -- with saying
5 it's a yes-or-no question. It is not a
6 yes-or-no question, and he's trying to
7 say that. Judge Vanaskie has already --
8 MR. SLATER: That's great.
9 You're obstructing this deposition very
10 early on. I don't appreciate it.
11 MR. BERNARDO: I disagree.
12 MR. SLATER: And please don't
13 threaten me with court action.
14 MR. BERNARDO: I didn't
15 threaten you with court action.
16 MR. SLATER: You did. You
17 did.
18 MR. BERNARDO: I'm just
19 observing --
20 MR. SLATER: You're wasting
21 time on my record right now.
22 MR. BERNARDO: Adam, I think
23 you're wasting time now.
24 BY MR. SLATER:

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1 Q. Answer the question.
2 Doctor, a new question.
3 As part of your review of this case,
4 did you consider whether ZHP failed to do anything
5 from an organic chemistry perspective that it
6 should have done?
7 MR. BERNARDO: Object to the
8 form of the question. Vague. Overly
9 broad. Asked and answered.
10 Go ahead, Dr. Xue.
11 THE WITNESS: As I said, I
12 really cannot say yes or no for this
13 question.
14 I'm an organic chemist. I --
15 I review what ZHP did. They did the
16 planning. They did the risk assessment.
17 They did the testings. And I also, of
18 course, read all the report from the
19 plaintiff side about these issues.
20 And then I went out myself.
21 As I pointed again and again, I'm a
22 chemist. I went out to just search for
23 the chemistry, what I rely on, what I
24 steps myself, and what I'm here for.

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1 So I read all these things.
2 That form the three points. I mean, for
3 -- for -- for ZHP, they did what they can
4 at the time the knowledge available to
5 them.
6 I hope -- I really hope that
7 answer your question.
8 BY MR. SLATER:
9 Q. I read your report. I saw no --
10 A. Excuse me.
11 Q. Okay. I'll start over.
12 I saw your report. I saw no
13 opinions critical of ZHP in your reports.
14 Were there any opinions in your
15 reports critical of ZHP?
16 MR. BERNARDO: Object to the
17 form of the question. Asked and
18 answered.
19 You can go ahead, Dr. Xue.
20 THE WITNESS: Are you asking
21 in my -- my report I'm facing now is
22 there any opinion criticizing ZHP?
23 BY MR. SLATER:
24 Q. That's my question.

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1 A. I have this report. I think the
2 opinions are there, right? So there that the
3 three bullets that we read upfront was my opinion.
4 Q. So the answer is, no, you have no
5 opinions in your report critical of ZHP; is that
6 correct?
7 MR. BERNARDO: Object to the
8 form of the question.
9 THE WITNESS: Well -- well, I
10 think we are -- we are making circles
11 here, right? So we talk about this for I
12 don't know how long, but this -- I
13 describe my view of my role here. I
14 stick with that.
15 I tried to be an expert to do
16 my job and tried to offer my opinion
17 based on my search, my understanding of
18 the case.
19 BY MR. SLATER:
20 Q. Doctor, do you know what you wrote
21 in your report?
22 A. I do. I wrote the report myself.
23 Q. Right.
24 Are there any opinions in your

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1 report critical of ZHP?
2 It's a yes-or-no question. I didn't
3 see any. I just want to confirm I didn't miss it.
4 MR. BERNARDO: Object to the
5 form of the question.
6 THE WITNESS: Well, I'll try
7 one more time.
8 I offered my opinion based on
9 what I search, what I learned, what I
10 read, and what I believe.
11 BY MR. SLATER:
12 Q. I did not see any opinions in your
13 report criticizing ZHP.
14 Am I correct that there are no
15 opinions you wrote in the report where you
16 criticized ZHP?
17 MR. BERNARDO: Object to the
18 form of the question. Asked and
19 answered.
20 Go ahead, Dr. Xue.
21 THE WITNESS: I have the
22 three opinions, right, out there. ZHP,
23 they did what they can, right? They
24 don't have -- based on what they have

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1 specifically at the time when all these
 2 processes they developing. That's what
 3 available to them. So that's what --
 4 what I form opinion.
 5 I'm not -- sometimes those --
 6 a lot of things it's not like absolute,
 7 right? So, yes, it must be like this.
 8 It must be like that, right?
 9 So I have to judge based on my
 10 own expertise, based on what other people
 11 talk, and what I learn from the science
 12 to come up with a reasonable, appropriate
 13 judgment of myself.
 14 I really think that that --
 15 that that's what I do here.
 16 BY MR. SLATER:
 17 Q. Did you read the deviation
 18 investigation reports written by ZHP?
 19 A. Well, I -- I read you know, right?
 20 So this is big case. I read so many documents.
 21 Q. Doctor, do you know what the
 22 deviation investigation reports are? Do you know
 23 what those documents are?
 24 A. I think those are -- if you -- do

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1 you have the document? Can we see the document
 2 together?
 3 Q. Sure.
 4 MR. SLATER: Let's put up the
 5 one that we've been talking about that we
 6 were talking about before. I guess it
 7 was Exhibit 210. The E318003 version 2.
 8 Put that on the screen.
 9 THE WITNESS: Will that be
 10 Exhibit Number 5?
 11 MR. SLATER: That will be
 12 Exhibit Number 5.
 13 (Document marked for
 14 identification as Xue Exhibit 5.)
 15 BY MR. SLATER:
 16 Q. For the record, he's uploading --
 17 we're uploading as Exhibit --
 18 For the record, we've uploaded
 19 Exhibit 5, which is the November 5, 2018 deviation
 20 investigation report titled "Investigation
 21 regarding unknown impurity" and then in
 22 parentheses "(genotoxic impurity) of Valsartan API
 23 (TEA process)."
 24 Do you have that? Do you see it?

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1 MR. SLATER: You can put it on
 2 the screen.
 3 THE WITNESS: I just got it
 4 loaded on my screen.
 5 As I said, I read so many
 6 things. This looks --
 7 BY MR. SLATER:
 8 Q. Doctor, I'm not asking you about all
 9 the things you read.
 10 I'm literally asking you: Have you
 11 read this document?
 12 A. I saw this document before, but as I
 13 said, if you want me -- ask me about details in
 14 here, I need to kind of -- you need to direct me
 15 there so I cite. I don't know. This --
 16 Q. Doctor.
 17 A. This is 300 pages.
 18 Q. Dr. Xue, we're going to do much
 19 better today if you answer the questions I'm
 20 answering and then don't go and tell me something
 21 else. Like I wasn't asking you about whether I'm
 22 going to ask you questions.
 23 I asked you one question. The
 24 question is: Did you see this deviation

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1 investigation report?
 2 A. I do.
 3 Q. Yes or no?
 4 A. I do.
 5 MR. BERNARDO: Object to the
 6 form of the question.
 7 BY MR. SLATER:
 8 Q. Did you consider this report in
 9 forming your opinions in this case?
 10 A. So all the document that's made
 11 available, I read them and then I judge, and then
 12 I decide to form my report. So in that case, yes,
 13 I did consider everything including this
 14 particular one to form my opinion.
 15 Q. As you sit here now, have you formed
 16 any opinions -- well, rephrase.
 17 As you sit here now, do you have any
 18 disagreement with any of the conclusions that ZHP
 19 formed and documented in this deviation
 20 investigation report?
 21 MR. BERNARDO: Object to the
 22 form of the question. Vague. Overly
 23 broad. Goes beyond the scope of his
 24 disclosure as an expert.

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1 Go ahead, Dr. Xue.
 2 MR. SLATER: Let's keep our
 3 objections to good-faith objections, too.
 4 MR. BERNARDO: You have to
 5 explain to me what remotely was in bad
 6 faith about an objection that, pursuant
 7 to Judge Vanaskie's instruction, gives
 8 you as simply as possible some
 9 understanding. That was as cryptic as I
 10 can be, Adam.
 11 MR. SLATER: Okay.
 12 THE WITNESS: Well --
 13 BY MR. SLATER:
 14 Q. Answer the question, Doctor.
 15 A. I will try to answer. Can you --
 16 the question is kind of long. Can you chop it
 17 into small pieces so I can handle?
 18 Q. Okay. Do you know what a deviation
 19 investigation report is? Do you know what this
 20 document is?
 21 A. Yes. This document was actually in
 22 2018 in July. That's after the nitrosamine was
 23 already known to be in some of the batches of the
 24 valsartan API, and then they did -- I think this

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1 is like a retrospective or backward study. That's
 2 my understanding about this.
 3 Q. Did you see that during the course
 4 of this report ZHP drew certain conclusions and
 5 made certain findings? Did you -- did you notice
 6 that when you read the report?
 7 MR. BERNARDO: Object to the
 8 form of the question. Overly broad.
 9 THE WITNESS: Right. As I
 10 said, this is like -- although you don't
 11 like my comments, but this is 300 pages.
 12 I honestly I don't have a super good
 13 memory about everything I read.
 14 If you can, please, if you can
 15 point to the section that you want me to
 16 address. Because I honestly I can't
 17 really just off my head to say everything
 18 or memorize everything you talk about
 19 here.
 20 I -- I really try my best
 21 tried to help everybody here.
 22 BY MR. SLATER:
 23 Q. It's not -- with all due respect, I
 24 don't need help. What I need is answers to my

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1 questions. So that's what I need.
 2 So I'm going to ask you this.
 3 I read your report. I did not see
 4 anywhere in your report where you said that any
 5 conclusion or finding by ZHP in its deviation
 6 investigation reports that you disagree with any
 7 of those conclusions or findings.
 8 Do you disagree with any of ZHP's
 9 conclusions or findings that were placed in their
 10 deviation investigation report?
 11 MR. BERNARDO: Object to the
 12 form of the question. Beyond the scope
 13 of his disclosure. Overly broad.
 14 Go ahead, Dr. Xue.
 15 THE WITNESS: Well, if you can
 16 show me.
 17 BY MR. SLATER:
 18 Q. No, I'm not. Doctor, let's stop
 19 right there. I'm not going to show you.
 20 MR. BERNARDO: No, no, no.
 21 Let's stop interrupting the witness,
 22 who's simply asking if you could show him
 23 something to refresh his recollection,
 24 he'll answer. Okay? So let's stop the

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1 interrupting each other.
 2 THE WITNESS: I'm --
 3 BY MR. SLATER:
 4 Q. That's not the question, though. So
 5 that's --
 6 A. I'm here --
 7 Q. I withdraw the question, Doctor,
 8 because we're -- we're honestly at some point I'm
 9 going to stop the deposition if I cannot get
 10 intelligible answers to questions, and I'm just
 11 going to send the transcript to the court and say
 12 that counsel needs to reprep their witness to be
 13 able to actually answer a question with a direct
 14 answer.
 15 It's not the ground we covered.
 16 MR. BERNARDO: Now I object.
 17 That's a threat. That's --
 18 MR. SLATER: No. I'm feeling
 19 very frustrated because I cannot get an
 20 answer to a question.
 21 BY MR. SLATER:
 22 Q. And so here's the question, Doctor.
 23 A. Yes.
 24 Q. If you disagreed with any of Z --

<p style="text-align: right;">Page 62</p> <p>1 well, let me ask the question differently. 2 As a general matter, you understand 3 that in the deviation investigation report, ZHP 4 analyzed why the NDMA and NDEA contamination 5 occurred in its valsartan API. 6 Do you understand generally that was 7 the purpose of this document? 8 A. That -- that's something. At least 9 to my understand, that's something included in 10 this study. 11 Q. Okay. Do you disagree with any of 12 the findings or conclusions by ZHP that they 13 documented in analyzing what happened? 14 MR. BERNARDO: Objection. 15 THE WITNESS: Well, here's -- 16 MR. BERNARDO: Wait a minute, 17 Doctor. 18 Object to the form of the 19 question. Vague. Overly broad. Beyond 20 the scope of his disclosure. 21 Go ahead, Dr. Xue. 22 THE WITNESS: Well, as I said, 23 right? So if you ask me whether I 24 disagree with some conclusion, I think I</p>	<p style="text-align: right;">Page 64</p> <p>1 I'm here as a chemist addressing the 2 experts' opinions from the plaintiff side. If 3 they raise anything, I try to address. I read the 4 whole thing. I, you know, I tried to look for my 5 scientific basis to address those. 6 I don't know why you think -- or 7 maybe I'm wrong -- I should actually be 8 responsible also for finding any evidence to prove 9 that ZHP did anything wrong. 10 Q. Doctor, I'm not trying to evaluate 11 anything other than to confirm that I didn't see a 12 particular opinion in your report. 13 So all I'm asking you is this. 14 You wrote a report dated 15 December 22, 2022. 16 A. Right. 17 Q. I don't see any opinion in that 18 report, which is 58 pages long, where you said 19 that ZHP made a finding or drew a conclusion in a 20 deviation investigation report that you disagree 21 with. 22 I just want to make sure that you 23 can confirm for me, "Yes, you're right, 24 Mr. Slater, I didn't form such an opinion and put</p>
<p style="text-align: right;">Page 63</p> <p>1 have at least the right to know what 2 conclusion you talk about here, right? 3 So also these regulatory work 4 is really -- we are moving kind of 5 outside of my -- my expertise. 6 I try to do everything that I 7 can to offer in my -- in my area, but if 8 you don't even show me what -- what 9 conclusion you are talking about here 10 and -- and what at least really chemistry 11 related or -- or it's not even my area. 12 I just don't want to get 13 anywhere that is -- is not my expertise. 14 I'm sorry. 15 BY MR. SLATER: 16 Q. Okay. I read your report very 17 carefully, Doctor. I did not see any opinions in 18 your report where you said that ZHP made a finding 19 in a deviation investigation report that you 20 disagree with. 21 There's no such opinion in your 22 report, right? 23 A. Well, because what we -- I think we 24 kind of moving back to the last question.</p>	<p style="text-align: right;">Page 65</p> <p>1 it in my report." That's all I'm asking. 2 Am I right? 3 MR. BERNARDO: Dr. Xue, he's 4 simply asking to confirm that what he 5 said is not written in your report. 6 Just -- 7 THE WITNESS: Right. 8 I think I answered that 9 because I have the three, three bullets, 10 three opinions I wrote clearly. Beyond 11 that, that's not my key opinions. I -- 12 yeah. So that means I don't have those 13 opinions. The three key opinions I 14 listed clearly in my report already. 15 That make sense to you? 16 BY MR. SLATER: 17 Q. You're holding yourself out as an 18 expert in this case as an expert in the field of 19 organic chemistry; is that correct? 20 A. Yes. 21 Q. Do you hold yourself out as an 22 expert with regard to the FDA? 23 A. Can you clarify what "FDA" mean 24 here?</p>

<p style="text-align: right;">Page 66</p> <p>1 Q. Are you holding yourself out as an 2 expert with regard to the FDA's oversight of the 3 API manufacturing process for drugs like 4 valsartan? 5 A. Can you also explain to me what 6 "oversight" mean? 7 Q. You don't know what "FDA oversight" 8 means? 9 A. I see oversight as like -- like 10 supervise, oversee. So but specifically, what do 11 you mean by "oversight"? Are you talking about 12 FDA regulations? 13 Q. I will ask it differently. 14 Are you holding yourself out as an 15 expert with regard to FDA regulation of the 16 development and manufacture of drug products? 17 A. On the regulation part, as I made it 18 clear, I'm not expert at all in regulatory 19 science. 20 But in term of drug development 21 or -- or those technical processes involving 22 organic chemistry, because the nature of my own 23 research and training, I have those background. 24 Q. The part you just told me about at</p>	<p style="text-align: right;">Page 68</p> <p>1 your question, not trying to cut you adding 2 additional useless information there. I'm really 3 trying to help. 4 Q. You're not holding yourself out as 5 an expert with regard to Good Manufacturing 6 Practices, correct? 7 A. I know GMP, but I'm -- I'm here, as 8 I said upfront, I'm an organic chemist. I'm here 9 for that, but I know GMP, but I'm not an expert in 10 those regulations so those -- those -- those rules 11 of things. 12 Q. From reading your CV, it's my 13 understanding that you do -- well, actually, why 14 don't you tell me in a simple short version what 15 it is that you do professionally. 16 A. I'm an associate professor. I do 17 therapeutic development. I own a lab. We -- we 18 -- we -- what we work on multiple projects try to 19 develop different drugs for different type of 20 human diseases. 21 Q. And I saw a term small molecule -- 22 "small molecule therapeutics"? 23 A. Yes. 24 Q. What does that mean?</p>
<p style="text-align: right;">Page 67</p> <p>1 the end of your answer is not what I asked you 2 about. 3 I asked about the FDA regulation of 4 drug development and drug manufacturing. 5 You're not an expert in that area, 6 correct? 7 A. Well, if that's, again, my language 8 apologize, but I think your question was not quite 9 what you are saying, right? 10 So you are saying I judge myself as 11 the expert in manufacturing, development. All 12 these are not just regulatory. These are -- these 13 are matching my field, right? These are reaction 14 involved, the chemistry involved and then you 15 have, you know, there are all these judgment, all 16 these assessment or testing, those are there, 17 right? 18 So, but if you talk about regulation 19 like what is required? What -- what -- what is 20 GMP? What -- what are those, you know, for 21 different things, APIs, what the standard of this? 22 That's where I am not. 23 I want to make it clear. This is 24 not -- I thought just now I was trying to answer</p>	<p style="text-align: right;">Page 69</p> <p>1 A. Thank you for reading my CV. 2 Q. What are small -- rephrase. 3 I saw in your CV the term "small 4 molecule -- 5 A. Yeah. 6 Q. -- therapeutics." What does that 7 mean? 8 A. Small molecule like, for instance, 9 we all know valsartan is a small molecule. So 10 therapeutics means drugs. Like valsartan, you 11 know, is a -- is a small molecule drug. So that's 12 what I do. 13 Q. You develop the -- the molecules 14 that actually are going to have an impact 15 physiologically on a person's body to address a 16 disease basically? 17 A. That's our goal. We haven't really 18 got anything on the market yet. 19 Q. Are you involved in the development 20 of a drug product for manufacture and sale on a 21 commercial basis? Meaning after you develop or 22 work on developing the molecule, are you then 23 involved in if a pharmaceutical company -- well, 24 let me ask the question differently.</p>

<p style="text-align: right;">Page 70</p> <p>1 Do you have any experience working 2 with the actual development of a manufacturing 3 process for large-scale manufacturing of a drug 4 product for commercial sale? Is that something 5 that you've done? 6 A. Well, for marketing, put things 7 advertisement or setting or, you know, all these, 8 I have no clue. I have never done those. 9 But for development, right? So for 10 just point out the FDA purpose, I never really 11 involved in the regulations or registers, all 12 these thing. Although we try and move there. 13 So, but what we do here is a lot of 14 research. It's close to identification, 15 synthesis, development, characterization of the 16 compound and, of course, we do animal variation, 17 big or small animals. So the goal is to put 18 things on market. 19 So I don't know whether that answer 20 your question. 21 So a lot of my thing, my -- my -- my 22 research scope is -- is stopped before like 23 packaging, dosing or -- or advertisement. 24 I don't know whether that answer</p>	<p style="text-align: right;">Page 72</p> <p>1 their project cross. 2 Just like zinc chloride like you use 3 as example. We don't do zinc chloride. We don't 4 do valsartan at all in our lab. But we -- 5 everybody has -- has some sort of project. 6 They all trying to make the compound 7 in the efficiency that they want, and then they 8 try to get the compound characterized in the high 9 quality as much as we want. And then they want to 10 make sure they can finish the project in a time 11 efficient way means they don't want to get caught 12 in trouble because they didn't plan well. 13 So all these are I think it's -- I 14 personally have never worked for any 15 pharmaceutical company in my career, but our lab, 16 the nature of the research -- I won't -- I won't 17 say. Maybe it's not the good analogy, but it's 18 like a mini pharmaceutical industry here ongoing 19 in my lab. 20 Q. Have you ever developed an API for 21 commercial manufacture? 22 A. You're asking whether I have 23 developed, right? So as I said, that's my goal, 24 right? So to, you know, to get a drug on market</p>
<p style="text-align: right;">Page 71</p> <p>1 your question. 2 Q. Well, let me give you -- try to do 3 it with using some of the terms from this case. 4 One of the manufacturing processes 5 at issue in this case we've referred to as the 6 zinc chloride process, correct? 7 A. Oh, yes. 8 Q. Okay. In your work, have you been 9 involved in developing a drug -- drug 10 manufacturing process such as like the zinc 11 chloride process? 12 Meaning the drug manufacturing at a 13 pharmaceutical company where they're actually 14 going to manufacture the pills from the API, etc., 15 that's not something you do, right? 16 A. Well, what you just described is a 17 little broad. Like as I said, right? So we don't 18 do manufacture in term of get to the dose like you 19 got really commercial boxes to the patient. We 20 don't do that. 21 However, my research or my work is a 22 lot of development, just like the -- the reaction. 23 I mean, we have to evaluate reaction. We have to 24 read. Everyday everybody in my lab has to have</p>	<p style="text-align: right;">Page 73</p> <p>1 to help people with their health. I haven't had 2 any drug named after me at this moment. 3 Q. Have you ever been involved in the 4 development of a manufacturing process for an API 5 for a pharmaceutical company to actually 6 manufacture the API? Has that something -- is 7 that something you've ever done? 8 A. So you asking whether I'm involved 9 in partnership with a -- with a pharmaceutical 10 company? 11 Q. In any capacity. 12 Have you ever done that? 13 A. So we have collaborative projects 14 sometimes with companies. I don't know whether 15 that -- that qualified or that's what you were 16 asking. But we -- as I said, we -- our research 17 nature is very close to pharmaceutical company 18 does. We don't worry about the product, you know, 19 formulations or dosing or advertisement or 20 selling. We don't. We never get in touch of 21 that, but everything else actually we do. 22 Q. Let's talk about valsartan and try 23 to talk in that context. 24 A. Sure.</p>

<p style="text-align: right;">Page 74</p> <p>1 Q. What you do is you try to develop -- 2 if we use -- if we used valsartan -- let me ask it 3 differently. 4 What you do is you try -- you're the 5 person who develops the valsartan molecule to 6 treat high blood pressure. 7 That's -- that's what you do 8 basically, right? 9 I know you didn't develop valsartan, 10 but by analogy, that's what your research is to 11 develop the actual -- the actual drug that's going 12 to actually -- the molecule, the valsartan 13 molecule. 14 That's basically what you'd be 15 developing, right? 16 A. That's not quite the same. 17 See, what we do is we have a 18 variation this compound. Let's see valsartan. As 19 you said, we don't do valsartan in the lab. I 20 just want to make it clear. 21 Valsartan is my target now. We need 22 to figure out how to make valsartan in the lab in 23 an efficient way because PhD thesis probably 24 depends on the time. So they need to be very</p>	<p style="text-align: right;">Page 76</p> <p>1 coming from something, right? So you're going to 2 have some design strategy there to come with a 3 structure. However, this is like a first sector, 4 first stage. 5 Then the next stage is also super 6 important is to make sure you produce in a timely 7 fashion and a quality fashion a nice molecule. So 8 you can use that for all the testing, PKs, PDs 9 animal studies, toxicologies. All these things we 10 do, that depends on the -- on the second sector 11 the synthesis. 12 So we have three sectors. Just now 13 you're saying I try to identify the structure. 14 That's absolutely a very, very important sector, 15 but it's not complete. 16 Q. Have you ever had input into the 17 development of a manufacturing process for an API? 18 MR. BERNARDO: Object to the 19 form of the question. Vague. 20 THE WITNESS: Right. So I 21 spent a little time just now. I thought 22 I made it fairly clear, right? 23 So what I don't do is, I don't 24 do those regulatories. When I -- when</p>
<p style="text-align: right;">Page 75</p> <p>1 carefully work with me, design a synthetic route, 2 and that would be used by the PhD student to get 3 the valsartan synthesized. 4 And then we want to make sure we 5 have good quality control of the valsartan product 6 that we got is in good shape. So that means you 7 can actually use that through all these testing. 8 And then we will -- we will -- we 9 will validate valsartan does control the blood 10 pressure in different models, in vitro, in vivo. 11 And then we will -- we will say, hey, FDA, we have 12 something. Please give us, you know, drug 13 approval. But that -- we never touch that yet. 14 That's the goal. 15 Q. Your focus is on developing the 16 structure of the drug to treat the medical 17 condition. That's what your research and that's 18 what your work is focused on. 19 Do I understand that? 20 A. Well, I think you -- your -- your 21 point is close, but not quite complete. Because 22 my work, yes, is very, very critical for my -- my 23 people to actually get the structure. 24 Like valsartan, you can imagine it's</p>	<p style="text-align: right;">Page 77</p> <p>1 you have a compound that's ready, we know 2 all everything was great. We just need 3 to make the pill and packaging. 4 We don't do that. We have no 5 expertise. We don't -- I honestly have 6 no interest in touching that in my 7 personal career. But what everything 8 else a drug development process requires, 9 my lab does them all. 10 BY MR. SLATER: 11 Q. Do you know what an API is? 12 A. Yes. 13 Q. What is an API? 14 A. It's active pharmaceutical -- excuse 15 me -- it's the ingredient. Sorry about that. 16 Q. In your career up to today -- 17 A. Yeah. 18 Q. -- have you ever been involved in 19 the development of the manufacturing process for 20 an API that was actually sold? 21 A. Well, to answer your question 22 like -- like yes or no question, right? So if 23 this is like -- you ask me whether I have a drug 24 on market. I thought I already told you. I hope</p>

<p style="text-align: right;">Page 78</p> <p>1 I do. This moment I don't have any drug already 2 be approved. We have multiple project on the way. 3 I also have grant -- I'm not having 4 yet. Hopefully, it will be founded. But have 5 pending grant at FDA. They try -- I try to, you 6 know, they are trying to fund me on something like 7 you said to develop directly an API on the market, 8 but not -- the grant is still pending. I cannot 9 -- I hope I can get it. 10 Q. So up till today, you've never been 11 involved in the development of an API that was 12 actually sold on the market, correct? 13 A. No, it's not correct, right? So -- 14 Q. So tell me -- then tell me -- 15 MR. BERNARDO: Wait, wait. 16 BY MR. SLATER: 17 Q. -- which supply you have developed 18 that's actually on the market? 19 MR. BERNARDO: Object to the 20 form of the question, and he said that's 21 not correct and clearly was -- 22 MR. SLATER: Actually, you 23 know what? I misstated my question 24 actually, and I meant to ask about the</p>	<p style="text-align: right;">Page 80</p> <p>1 MR. BERNARDO: Object. 2 THE WITNESS: Yeah. 3 MR. BERNARDO: Let's stop 4 interrupting the witness's question. 5 MR. SLATER: How about we 6 suggest to our witness to answer the 7 question directly? I think we both have 8 objections here. 9 THE WITNESS: I -- I really 10 trying, right? So I said if you ask me 11 whether I have a drug on market after my 12 name -- 13 BY MR. SLATER: 14 Q. I'm not asking that. 15 A. I don't -- 16 Q. Don't answer that, Doctor. 17 I didn't ask you about your name or 18 whether you own the drug. That's not the question 19 I asked. 20 So let's try to focus on the 21 question now. 22 A. Yeah. 23 Q. Let's be precise. 24 A. Right.</p>
<p style="text-align: right;">Page 79</p> <p>1 manufacturing process. 2 BY MR. SLATER: 3 Q. Let me ask you this differently. 4 So am I correct that up until today, 5 you have not yet ever developed or been involved 6 in the development of the manufacturing process 7 for an API that was actually sold on the market? 8 Have you ever done that up till 9 today? 10 MR. BERNARDO: Object to the 11 form of the question. Asked and 12 answered. 13 BY MR. SLATER: 14 Q. It's a yes or no, sir. 15 MR. BERNARDO: Object to the 16 form of the question. 17 THE WITNESS: You keep 18 saying. You keep saying the question yes 19 or noes. I also try to answer if it can 20 be a yes or no, but it is not, right? 21 BY MR. SLATER: 22 Q. Have you -- 23 A. I said -- 24 Q. Have you --</p>	<p style="text-align: right;">Page 81</p> <p>1 Q. Up until today, have you ever been 2 involved in the development of the manufacturing 3 process for any API that was actually sold on the 4 market? 5 MR. BERNARDO: Object to the 6 form of the question. 7 BY MR. SLATER: 8 Q. Yes or no. Have you done that or 9 have you not done it? 10 A. Yeah. So I think I get the 11 question. 12 If you ask me whether any of the 13 market drug at this moment was developed by me, 14 the answer is, no, I haven't developed any drug 15 that is sold on market at this moment. 16 I hope my next drug will be sold on 17 market next year or very soon. We are doing 18 those, but I hope it's in the near future. 19 If you say right now, Dr. Xue, if 20 you have any drug already sold or you involve in 21 any compound that is already be sold on market, 22 it's not, but it doesn't mean I'm not doing those, 23 right? 24 MR. BERNARDO: Adam, we've</p>

<p style="text-align: right;">Page 82</p> <p>1 been going about an hour and 15. If this</p> <p>2 is a good breaking point?</p> <p>3 MR. SLATER: I'm ready to keep</p> <p>4 going. So you guys like to do your hour</p> <p>5 break. You do whatever you want. If you</p> <p>6 want to stop the deposition and take a</p> <p>7 break, you have the right to do it. I</p> <p>8 don't need a break.</p> <p>9 MR. BERNARDO: Dr. Xue, would</p> <p>10 you like a break?</p> <p>11 THE WITNESS: Yes.</p> <p>12 MR. BERNARDO: Okay. We'll</p> <p>13 take a break.</p> <p>14 MR. SLATER: See you in 10</p> <p>15 minutes.</p> <p>16 THE VIDEOGRAPHER: Time right</p> <p>17 now is 11:17 a.m. We're off the record.</p> <p>18 (Recess.)</p> <p>19 THE VIDEOGRAPHER: Time right</p> <p>20 now is 11:29 a.m. We're back on the</p> <p>21 record.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Dr. Xue, do you utilize gas</p> <p>24 chromatography in your lab?</p>	<p style="text-align: right;">Page 84</p> <p>1 does someone else do that?</p> <p>2 A. I sometimes do that myself.</p> <p>3 Sometimes my student do them. Sometimes if it's</p> <p>4 high-end experiment, the collaborators in the mass</p> <p>5 spec center will do that themselves just to</p> <p>6 protect the improvement.</p> <p>7 Q. Have you ever used any form of</p> <p>8 chromatography or mass spectrometry to try to</p> <p>9 identify a nitrosamine in a substance?</p> <p>10 A. I never used -- you said</p> <p>11 chromatography -- either GC or LC to identify</p> <p>12 nitrosamine in my career.</p> <p>13 Q. Have you ever used mass spectrometry</p> <p>14 to try to isolate or identify a nitrosamine?</p> <p>15 A. I never in my career do that.</p> <p>16 Q. Do you hold yourself out as an</p> <p>17 expert with regard to the formation and</p> <p>18 identification of nitrosamines?</p> <p>19 A. You're asking I view myself as an</p> <p>20 expert for the formation and you said isolation as</p> <p>21 well for nitrosamine?</p> <p>22 Q. Do you hold yourself out as an</p> <p>23 expert with regard to the identification and</p> <p>24 formation of nitrosamines?</p>
<p style="text-align: right;">Page 83</p> <p>1 A. In my lab, we don't use gas</p> <p>2 chromatography.</p> <p>3 Q. Have you ever used gas</p> <p>4 chromatography for any of your work?</p> <p>5 A. In graduate school, we used GC for</p> <p>6 some works when I was a graduate student. But,</p> <p>7 you know, in general speaking, because the nature</p> <p>8 of my research, we work on molecules that are not,</p> <p>9 like very small, like a solvent size.</p> <p>10 So we do mass spec. We -- we do</p> <p>11 chromatography but usually liquid chromatography.</p> <p>12 They are same concept but different nature because</p> <p>13 the requirement of the size of the molecule.</p> <p>14 Q. You utilize -- rephrase.</p> <p>15 Do you use liquid chromatography in</p> <p>16 your -- in your work?</p> <p>17 A. Yes.</p> <p>18 Q. Do you use --</p> <p>19 A. Instead of GC.</p> <p>20 Q. Do you use liquid</p> <p>21 chromatography-mass spectrometry in your work?</p> <p>22 A. I do use L -- we call it LC-MS --</p> <p>23 liquid chromatography-MS in my work a lot.</p> <p>24 Q. Do you operate the LC-MS machine or</p>	<p style="text-align: right;">Page 85</p> <p>1 A. Thank you for repeating.</p> <p>2 For nitrosamines specifically as a</p> <p>3 class of compound, I never did in my research.</p> <p>4 But in term of small molecule characterization and</p> <p>5 formation, we do that on daily basis. That's the</p> <p>6 nature the majority of our research do.</p> <p>7 Q. When did you first learn of the NDMA</p> <p>8 and NDEA contamination of valsartan?</p> <p>9 A. When I start to get involved in this</p> <p>10 case, I learned these two small molecules NDMA and</p> <p>11 NDEA contamination for valsartan API.</p> <p>12 Q. According to the invoices that we</p> <p>13 were provided, your first meeting took place</p> <p>14 November 18, 2022 with Jessica and Allison.</p> <p>15 Is that the first time you were</p> <p>16 contacted regarding this case?</p> <p>17 A. I don't remember exactly the date I</p> <p>18 put. It's a while ago, but that was not the first</p> <p>19 time I was contacted.</p> <p>20 Q. The date of the first meeting on</p> <p>21 your invoice is November 18, 2022.</p> <p>22 When were you first contacted?</p> <p>23 A. I believe it's probably three, maybe</p> <p>24 four days before that first meeting. I really</p>

<p style="text-align: right;">Page 86</p> <p>1 honestly don't remember exact how many days. 2 Q. I don't know I need -- I don't need 3 to know the exact date. 4 A. Okay. A few -- a few days before 5 the meeting, Jessica Miller, Ms. Jessica Miller 6 called me. 7 Q. So you first learned about the NDMA 8 and NDEA contamination of valsartan in November 9 2022, correct? 10 A. Yes. 11 Q. In terms of the root cause for the 12 formation of the NDMA -- you understand what root 13 cause means? 14 A. If I understand correctly, root 15 cause is like why. Is that the correct meaning of 16 root cause? 17 Q. We can go with that for now. 18 A. Okay. Thank you. 19 Q. If we boil down the root cause to 20 the very simple, the most -- the most fundamental 21 reason why this, the NDMA formed in the zinc 22 chloride process -- 23 A. Your voice was chopped off because 24 it was -- I think the Internet. Can you repeat</p>	<p style="text-align: right;">Page 88</p> <p>1 THE WITNESS: The quenching 2 process of the -- you said the zinc 3 chloride process, right? 4 BY MR. SLATER: 5 Q. Let me start over. 6 A. Okay. 7 Q. You know what? Actually, I'm not 8 going to waste my time with this. 9 Let's now talk about a couple other 10 things. 11 In your report, at one point you 12 talk about reaction environments. 13 When you use the term a "reaction 14 environment," would an example of a reaction 15 environment be the zinc chloride process? 16 A. You want me to provide an example or 17 you want -- 18 Q. No. I just want to know if 19 that's -- if my understanding is correct or not. 20 A. What was your understanding? So 21 you -- 22 Q. Is an example of a reaction 23 environment the zinc chloride process? 24 A. A zinc chloride process is multiple</p>
<p style="text-align: right;">Page 87</p> <p>1 what you just say? 2 Q. Sure. 3 Was the quenching of valsartan with 4 sodium nitrite part of the root cause for the 5 creation of the NDMA in the zinc chloride process? 6 A. I apologize, but just now your voice 7 was still -- you freeze for like three seconds. 8 MR. SLATER: Am I freezing? 9 BY MR. SLATER: 10 Q. Might be on your end. 11 MR. BERNARDO: I think, 12 Dr. Xue, it might be on your end because 13 he was pretty clear on my end. 14 THE WITNESS: I heard you 15 talk about sodium nitrate, but before 16 that there were three second I didn't 17 quite hear what you say. 18 BY MR. SLATER: 19 Q. Was the quenching with sodium 20 nitrite as part of the zinc chloride process an 21 important part of why the NDMA formed? 22 MR. BERNARDO: Object to the 23 form of the question. Vague. 24 Go on.</p>	<p style="text-align: right;">Page 89</p> <p>1 step. It's -- I think we can call it four or five 2 steps, right? Reaction in the environment is a 3 specific set of conditions that's specific for the 4 particular reaction. 5 It's -- it's -- I think for zinc 6 chloride process, it's too big of a scope for 7 environment because you want to -- you want to be 8 more specific on what specific reaction you talk 9 about. 10 Q. Would the tetrazole ring formation 11 step of the zinc chloride process be an example of 12 a reaction environment? 13 A. Yes, you can say that. 14 Q. Would the quenching step be a 15 reaction environment? 16 A. Quenching step is also, yes. It's a 17 -- we usually call it reaction conditions, but 18 yeah. So environment is similar to conditions. 19 Q. One of the points that you make in 20 your -- rephrase. 21 One of the subjects that you address 22 in your report is the temperature at which the 23 zinc chloride tetrazole ring formation step took 24 place at.</p>

<p style="text-align: right;">Page 90</p> <p>1 You discuss temperature in your</p> <p>2 report, right?</p> <p>3 A. I did.</p> <p>4 Q. And if I understand your opinion,</p> <p>5 it's your opinion that the temperature that the</p> <p>6 DMF was subjected to was too low for DMA to form.</p> <p>7 Is that your opinion?</p> <p>8 A. My opinion is ZHP at that moment,</p> <p>9 not now, but when they actually develop and use</p> <p>10 the zinc chloride process, they have no idea that</p> <p>11 DMF can actually decompose at the temperature that</p> <p>12 they run. I believe is 135 -- 335 degrees C.</p> <p>13 Q. Are you aware that ZHP never even</p> <p>14 considered the question of whether or not the DMF</p> <p>15 could degrade during the process?</p> <p>16 Are you aware they did not even</p> <p>17 consider the question or analyze it at all?</p> <p>18 A. So you're asking --</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 question.</p> <p>21 THE WITNESS: -- me to confirm</p> <p>22 that ZHP never aware that the</p> <p>23 decomposition of DMF could actually take</p> <p>24 place in their tetrazole reaction? Is</p>	<p style="text-align: right;">Page 92</p> <p>1 MR. BERNARDO: Then you</p> <p>2 shouldn't engage me, Adam.</p> <p>3 MR. SLATER: I'm not going to.</p> <p>4 That's the last time it will happen</p> <p>5 today.</p> <p>6 MR. BERNARDO: Perfect.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Can you answer the question, Doctor?</p> <p>9 A. I'm sorry. Can you repeat? I just</p> <p>10 got lost.</p> <p>11 Q. Sure. Sure.</p> <p>12 Are you aware that ZHP did not</p> <p>13 consider the question of whether or not DMF could</p> <p>14 degrade during the zinc chloride process to give</p> <p>15 off dimethylamine?</p> <p>16 Are you aware they never even</p> <p>17 thought about the question of whether or not it</p> <p>18 could happen?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question.</p> <p>21 THE WITNESS: Well, based on</p> <p>22 what I read, right, there's really not</p> <p>23 much available. They were not -- they</p> <p>24 didn't know and there's not actually</p>
<p style="text-align: right;">Page 91</p> <p>1 that your question?</p> <p>2 BY MR. SLATER:</p> <p>3 Q. My question was different.</p> <p>4 My question is: Are you aware that</p> <p>5 ZHP didn't even consider the question, didn't even</p> <p>6 think about the question of whether or not the DMF</p> <p>7 could degrade under the conditions of the zinc</p> <p>8 chloride process?</p> <p>9 Are you aware they never even</p> <p>10 thought about that?</p> <p>11 MR. BERNARDO: Object to the</p> <p>12 form of the question. Vague. Beyond the</p> <p>13 scope of his --</p> <p>14 MR. SLATER: You're objecting?</p> <p>15 There's a stipulation that you entered</p> <p>16 into with me on this point.</p> <p>17 MR. BERNARDO: Well, then, you</p> <p>18 don't need to ask this witness about it.</p> <p>19 MR. SLATER: All right. Let's</p> <p>20 not go back and forth. You and I, we</p> <p>21 should not communicate during this</p> <p>22 deposition. It's not going well.</p> <p>23 BY MR. SLATER:</p> <p>24 Q. Doctor --</p>	<p style="text-align: right;">Page 93</p> <p>1 reasonable to expect them to know.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Can you answer my question now?</p> <p>4 A. So the question was, did I aware</p> <p>5 they didn't even consider, right?</p> <p>6 I cannot speculate for other people</p> <p>7 whether they consider or not, but my research</p> <p>8 under my told me that, first of all, they didn't</p> <p>9 know. Second, they have not reasonably be</p> <p>10 expected to know this.</p> <p>11 That's my -- I -- I cannot say -- I</p> <p>12 cannot speak for ZHP, right?</p> <p>13 Q. Well, you're an expert in this case.</p> <p>14 Do you understand that you're</p> <p>15 supposed to be objective?</p> <p>16 MR. BERNARDO: Object to the</p> <p>17 form of the question. We're getting --</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Let me ask the question differently</p> <p>20 because counsel didn't like my question.</p> <p>21 Did you try to be objective in this</p> <p>22 case?</p> <p>23 It's a simple yes or no. Did you</p> <p>24 try to be objective?</p>

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1 A. Yes.

2 Q. So if you want to be an objective

3 expert, you want to see, well, did ZHP do anything

4 wrong?

5 That's one of the things you should

6 have been thinking about to be an objective

7 expert, right?

8 MR. BERNARDO: Object to the

9 form of the question. Argumentative.

10 BY MR. SLATER:

11 Q. Correct?

12 A. I consider everything come to me to

13 decide what I believe is correct or what I believe

14 is wrong.

15 Q. Okay. In forming your opinions, you

16 had to rely on the facts that were provided to

17 you, right? You had to rely on the facts,

18 correct?

19 A. For that I definitely agree, I rely

20 on the fact. I rely on everything that actually

21 provided I found around this topic.

22 Q. Okay. And in terms of the facts

23 that you relied on, did you understand whether or

24 not ZHP even considered the possibility that DMF

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1 could degrade potentially in the zinc chloride

2 process? Did they even look at that question at

3 all? Do you know? Yes or no.

4 A. Well, I -- I cannot say yes or no

5 because how can I read other people's mind, right?

6 I can only judge based on my understanding is they

7 don't know, and they did not expected to know.

8 Q. Based on everything you read --

9 A. Right.

10 Q. -- what is your understanding about

11 whether or not ZHP even thought about the question

12 of whether or not the DMF could degrade during the

13 zinc chloride process?

14 MR. BERNARDO: Object to the

15 form of the question.

16 BY MR. SLATER:

17 Q. What is your understanding of

18 whether they even thought about the question at

19 all?

20 A. My understanding or my feeling is

21 they didn't.

22 Q. Your opinion is, if they thought

23 about it, that you don't think they would have

24 found out information that they later found out,

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1 right?

2 MR. BERNARDO: Object to the

3 form of the question. Vague.

4 THE WITNESS: I didn't quite

5 understand your question.

6 BY MR. SLATER:

7 Q. Forget the question. We'll get --

8 we'll walk you through it with documents in front

9 of your face. We'll do it that way when we get to

10 that.

11 Okay. Are you an expert --

12 rephrase.

13 Do you believe that it's within your

14 expertise to give an opinion as to whether or not

15 ZHP should have thought about the question of

16 whether or not the DMF could degrade during the

17 zinc chloride process?

18 A. You're asking whether my opinion is

19 ZHP should have thought of this degradation as a

20 potential? You're asking that?

21 Q. You believe -- you believe that

22 question, that you're an expert in answering that

23 question?

24 A. I'm sorry. I don't think I clearly

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1 understand what you're asking because there's a

2 couple of curves in the question itself.

3 Q. You're holding yourself out as an

4 expert in organic chemistry in this case, right?

5 A. Yes.

6 Q. In terms of what the chemists at a

7 drug manufacturing company called ZHP should have

8 thought about in performing their risk assessment

9 for the zinc chloride process, is that within your

10 expertise what questions they should have thought

11 about in developing the process?

12 A. Yes.

13 Q. Okay. In your opinion, should ZHP's

14 -- rephrase.

15 In your opinion, should ZHP have at

16 least thought about the question of whether or not

17 DMF could introduce DMA into the zinc chloride

18 process? Should they have considered the

19 question?

20 A. I don't think there's available

21 information for them during the time when this

22 chemistry was developed to -- to trigger that

23 thought. But, again, I cannot speak for them, but

24 that's my understanding. So there's -- there's

<p style="text-align: right;">Page 98</p> <p>1 not enough to say that.</p> <p>2 Q. Is one of your opinions -- well,</p> <p>3 rephrase.</p> <p>4 Do you agree with me that the DMF</p> <p>5 was capable of degrading to form dimethylamine</p> <p>6 during the zinc chloride process? Yes or no.</p> <p>7 A. You ask me now?</p> <p>8 MR. BERNARDO: Wait, wait,</p> <p>9 wait.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. I'm asking you now. As you sit here</p> <p>12 right now, is the answer yes or no?</p> <p>13 MR. BERNARDO: Object to the</p> <p>14 form of the question. Vague.</p> <p>15 Go on, Dr. Xue.</p> <p>16 THE WITNESS: Right.</p> <p>17 If you ask me now after I</p> <p>18 involve in this case and reading this</p> <p>19 reaction like hundred times over the last</p> <p>20 month. So now, yes, I know.</p> <p>21 But we are not talk about the</p> <p>22 reaction happen right now, right? So I</p> <p>23 -- it's not also not talk. Maybe talk</p> <p>24 about ZHP when they try to develop this</p>	<p style="text-align: right;">Page 100</p> <p>1 already said, right? So they really have no</p> <p>2 reason to do so because they don't know. It could</p> <p>3 be a possible factor.</p> <p>4 Q. Well, Dr. Xue.</p> <p>5 A. Yes.</p> <p>6 Q. You've been telling me what they</p> <p>7 could or could not have known. I haven't asked</p> <p>8 you that question.</p> <p>9 I asked you if they did certain</p> <p>10 tests. So I would appreciate if you could limit</p> <p>11 your answers to the actual questions I ask instead</p> <p>12 of talking about things I'm not asking you about.</p> <p>13 Can you do that for me, please?</p> <p>14 MR. BERNARDO: And I would</p> <p>15 appreciate if your questions and your</p> <p>16 comments to the witness were not</p> <p>17 argumentative and if you would conduct</p> <p>18 yourself appropriately for an expert</p> <p>19 deposition.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Can we do that, Dr. Xue?</p> <p>22 I would appreciate it if I ask a</p> <p>23 question about one thing if you don't talk about</p> <p>24 another thing. It would make the deposition go</p>
<p style="text-align: right;">Page 99</p> <p>1 in 2013 or 2014, that's a totally</p> <p>2 different situation.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Did ZHP do any lab scale testing to</p> <p>5 replicate the temperatures the zinc chloride</p> <p>6 process would subject the DMF to in order to see</p> <p>7 whether or not DMA would form under those</p> <p>8 conditions?</p> <p>9 I'm just asking if they did any</p> <p>10 tests of that question when they developed the</p> <p>11 zinc chloride process. Yes or no.</p> <p>12 A. Well, again, there are things I</p> <p>13 read. If you want to discuss about a specific</p> <p>14 document, I prefer if you can put it up so we can</p> <p>15 discuss specifically.</p> <p>16 But if you ask me off my head</p> <p>17 whether they did a lab scale testing of -- they</p> <p>18 did lab scale quality control when they actually</p> <p>19 do the risk assessment. When they try to make the</p> <p>20 switch from the -- the previous -- I think it's</p> <p>21 TEA process with quenching to the zinc chloride.</p> <p>22 They did this assessment on the lab</p> <p>23 scale. I don't think they did this -- this --</p> <p>24 this test about whether DMA is there. Because I</p>	<p style="text-align: right;">Page 101</p> <p>1 smoother, okay?</p> <p>2 A. I'll try my best.</p> <p>3 Q. Thank you.</p> <p>4 Based on your review of the</p> <p>5 materials, you saw no evidence that ZHP actually</p> <p>6 did any tests, whether in the lab or at any other</p> <p>7 stage, where they ever actually tested to see if</p> <p>8 they subjected the DMF to the conditions it would</p> <p>9 be subjected to in the zinc chloride process</p> <p>10 whether or not it would degrade to give off</p> <p>11 dimethylamine.</p> <p>12 No such test was performed to your</p> <p>13 knowledge, correct?</p> <p>14 MR. BERNARDO: Object to the</p> <p>15 form of the question. Asked and</p> <p>16 answered.</p> <p>17 Go ahead.</p> <p>18 THE WITNESS: As I said, in</p> <p>19 test, they didn't test the formation of</p> <p>20 DMA during the process during the</p> <p>21 development. That's because at that</p> <p>22 time, they don't know that they need to</p> <p>23 test that.</p> <p>24 BY MR. SLATER:</p>

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1 Q. Why did you throw in the last part
2 "that's because" when I didn't ask you about the
3 reason? I just asked whether they did the test or
4 not. So why did you throw in the other part?
5 A. I just want amore complete answer.
6 Q. But I didn't ask that question. So,
7 I mean, the more complete answer could be
8 everything you know. I just would appreciate if
9 you would limit your answers to the question I
10 ask.
11 MR. BERNARDO: Object.
12 THE WITNESS: I will keep
13 that in mind. Thank you.
14 BY MR. SLATER:
15 Q. If I understand your opinion, it's
16 that ZHP -- withdrawn.
17 In your opinion -- well, rephrase.
18 Is it your opinion that the only way
19 that the dimethylamine was -- was introduced to
20 the zinc chloride process was during the tetrazole
21 step when the heating was to 135 plus or minus
22 degrees Celsius? Is that when you believe the DMA
23 was introduced to the process?
24 A. When I look at the process, right?

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1 So that's something the plaintiffs' expert point
2 out. So I was just focused on that step and then
3 look at this step.
4 Q. Is that your opinion?
5 MR. BERNARDO: He's finishing
6 his answer, Adam, please.
7 THE WITNESS: I'm trying to
8 finish. If you can let me. Thank you.
9 Right. So I -- I look at
10 the -- the opinion from the -- the expert
11 from the plaintiff side and that's what
12 they were saying. So I tried to address
13 that and I tried to.
14 Right now based on all the
15 result already out there, yes. So I feel
16 the degradation from DMF is likely the
17 reason why.
18 Although I, as a scientist,
19 before reading the study from FDA labs or
20 ZHP or other companies, they have a
21 conclusion. I won't just say for sure
22 this will be the cause or that will be
23 cause because I'm, you know, this must be
24 -- there must be some scientific studies

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1 around this problem to be performed, and
2 then that will give us a clear answer for
3 this question.
4 BY MR. SLATER:
5 Q. Do you have an opinion, as you sit
6 here right now, as to how the DMA was introduced
7 to the zinc chloride process?
8 This is a yes-or-no question. I
9 want to know if you have an opinion as to how it
10 happened.
11 MR. BERNARDO: Object to the
12 form of the question.
13 BY MR. SLATER:
14 Q. I just want to know if you have the
15 opinion. I'm not even asking what the opinion is.
16 Yes or no. Do you have an opinion
17 on that?
18 A. You ask me for opinion that DMA was
19 formed during the zinc chloride --
20 Q. Not what I asked you, Doctor. You
21 need to listen to my question, please.
22 Do you have an opinion as to how the
23 DMA was introduced to the zinc chloride process?
24 Yes or no.

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1 A. I do.
2 Q. In simple terms, what is your
3 opinion as how the DMA was introduced to the zinc
4 chloride process?
5 A. The DMA can actually form from
6 different ways.
7 Q. I'm asking what your opinion is to a
8 reasonable --
9 A. Right.
10 Q. -- degree of scientific certainty as
11 to how it happened in the zinc chloride process.
12 If you have that opinion, tell me.
13 If you don't know or you're not sure, you can say,
14 "I don't know" or "I'm not sure."
15 A. Well, degradation of DMF is one of
16 those, right? And there's other conditions
17 involved in the tetrazole formation step. The
18 zinc chloride. I don't know, right. So there
19 might be. Also other factors.
20 As I said, that's my feeling.
21 Because now we know DMA is in there and nobody
22 does any project to figure out how, right? So my
23 opinion is I said, yes, degradation from DMF is
24 suspicious.

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1 Q. Is it your understanding that nobody
2 has tried to figure out how the DMA got into the
3 zinc chloride process?
4 MR. BERNARDO: Object to the
5 form of the question.
6 THE WITNESS: Are you asking
7 me my understanding is nobody means?
8 BY MR. SLATER:
9 Q. Doctor, you just said to me nobody
10 tried to figure it out. I'm literally repeating
11 your answer to you.
12 A. No. At this -- well, I haven't seen
13 any result from any publication or announcement
14 saying what is the exact reason that dimethylamine
15 was formed. I haven't seen that.
16 Q. Okay.
17 A. If you have a document, I'd like to
18 see that document.
19 Q. Well, what I'm trying to figure out
20 is what you know to form -- to support the
21 opinions you've given in this case. My goal right
22 now is not to educate you and get new opinions.
23 So I'm trying to figure out what you
24 know now. Okay?

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1 A. What I know now is -- is -- is
2 during the zinc chloride process, somehow during
3 that zinc -- during that tetrazole formation step,
4 there are dimethylamine formed. I don't know
5 exactly because, again, I'm a scientist. Until I
6 see a definite experimental evidence, I cannot see
7 anything. I suspect that's the degradation of DMF
8 maybe with some sort of assistance from other
9 reagent used in combination. I don't know, but
10 that's my -- my feeling at this moment.
11 Q. So you agree with me that DMF was
12 capable of degrading at the temperatures it was
13 exposed to during the zinc chloride process and
14 forming dimethylamine, correct?
15 MR. BERNARDO: Object to the
16 form of the question.
17 BY MR. SLATER:
18 Q. You agree with that as you sit here
19 right now, correct?
20 MR. BERNARDO: Object.
21 THE WITNESS: I don't agree.
22 I think I made it clear.
23 This is one of the
24 possibilities. It's a chance, I suspect.

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1 I use the word "suspect" that can be
2 actually happen.
3 I also said that the other
4 conditions involving the reaction can
5 actually contribute, which nobody did
6 research yet. Until we have some sort of
7 publication on this case, I don't think I
8 can agree with anybody's speculation.
9 BY MR. SLATER:
10 Q. So I'm going to come back to the
11 question I asked you a few minutes ago because
12 you're telling me there's possibilities, but
13 you're not sure which one happened.
14 What I need to know is: Do you hold
15 an opinion now to a reasonable degree of
16 scientific certainty where you can say more likely
17 than not the DMA was introduced to the zinc
18 chloride process through this means?
19 Do you have an opinion as to that?
20 Not it could be a bunch of things,
21 but do you have an opinion as to what it was that
22 actually caused the DMA to be introduced to the
23 zinc chloride process? Yes or no.
24 A. I don't have a specific reason to

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1 say exactly this must be the road that DMA has
2 been formed during this step. I don't have that.
3 Because how can I have something which no research
4 has been done on this?
5 Q. All right. Let's go back to the
6 deviation investigation report that we marked
7 earlier.
8 What did we mark it as?
9 A. Which? Can you remind me the number
10 again?
11 Q. Yeah, I can. It's Exhibit --
12 MR. BERNARDO: 5?
13 MR. SLATER: It's Exhibit 5.
14 Exactly.
15 MR. BERNARDO: Wow.
16 BY MR. SLATER:
17 Q. And let's go to --
18 A. So can you remind me the number of
19 the file? Number?
20 MR. BERNARDO: It's Exhibit 5,
21 Dr. Xue.
22 THE WITNESS: Yeah, Exhibit
23 file number 3.
24 MR. BERNARDO: Oh, I don't.

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1 THE WITNESS: On my list.
2 Can somebody?
3 BY MR. SLATER:
4 Q. Let's go in that document to page
5 170.
6 MR. BERNARDO: Adam, one
7 second. He's asking -- I'm trying to
8 look where -- he's trying to pull it up
9 where --
10 THE WITNESS: 5 exhibit?
11 Which one?
12 BY MR. SLATER:
13 Q. Exhibit 5, the deviation
14 investigation report.
15 A. Number 5?
16 Okay. I'm on that report. Thank
17 you.
18 Q. Let's go to page 9 of 236 within
19 that report.
20 A. To you said page 9 of 236?
21 Q. Yeah. You see at the top right
22 there? You see -- see on the screen, Doctor?
23 Look on the screen.
24 A. Oh.

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1 Q. You see page 9?
2 A. Okay. Thank you for highlighting me
3 that. Let me --
4 Q. You can also look at it on your
5 screen. You can do whatever you want.
6 A. Okay.
7 Q. Do you see the page I'm asking you
8 about, page 9 of 236?
9 A. I am.
10 Q. And you can see that on page 9 of
11 236, ZHP conducted lab scale trials.
12 You see that in the middle of the
13 page? It says:
14 "For further confirmation, the
15 following lab scale trials were designed and
16 performed to verify the concluded formation
17 mechanism of NDMA."
18 Do you see that?
19 A. I see that section and the Table
20 3-1.
21 Q. And it says:
22 "The amount of NDMA formed by
23 quenching under different temperatures is shown in
24 the table below."

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1 Do you see that?
2 A. I see that table, the conditions.
3 Q. And you see that they subjected the
4 DMF plus zinc chloride to react at 135 degrees
5 Celsius for 20 hours, and they talk about what
6 they did and eventually added the sodium nitrite
7 later.
8 Do you see that?
9 A. Yes.
10 Q. And you see the NDMA in parts per
11 million that was produced by these various
12 experiments?
13 A. There's a column called "NDMA
14 (ppm)," right. That's the column you talk about,
15 right?
16 Q. Right.
17 A. Okay.
18 Q. Right. Have you ever seen this page
19 before right now?
20 A. Yeah, I don't remember exactly
21 whether I see this page, but, yeah, I do read this
22 document before.
23 Q. I didn't see anything in your report
24 where you talked about the fact that ZHP actually

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1 performed lab scale trials where they proved that
2 under the conditions of the zinc chloride process,
3 NDMA would form from the DMF and the sodium
4 nitrite.
5 Do you see that?
6 Let me withdraw it and ask it again.
7 I don't see any discussion in your
8 report about the lab scale trials that were
9 performed by ZHP to prove that the NDMA could form
10 under the conditions of the zinc chloride process.
11 You don't talk about that in your
12 report, right?
13 MR. BERNARDO: Object to the
14 form of the question. Assumes facts.
15 THE WITNESS: I didn't talk
16 about that in my report because I thought
17 that's -- that's the best of fact, right?
18 So we already by the year of
19 2018 knew that these impurity can
20 actually form as a side product in the
21 reaction that they try to do for the
22 tetrazole formation. I think that's the
23 fact, right?
24 So I didn't know that I have

<p style="text-align: right;">Page 114</p> <p>1 to repeat what the fact is. And these 2 experiment was this period is to try to 3 figure out, as you highlight here, at 4 different conditions how much of NDMA can 5 form. 6 I think that that's kind of a 7 backward looking back from 2018. Say, 8 oh, now we know under the condition that 9 I perform the tetrazole formation 10 reaction, there is. That's a conclusion 11 already draw, and then they look back to 12 try to change the condition to figure out 13 which parameter maybe play a bigger role. 14 And it looks like to me all 15 the six entries they actually did, they 16 all form some, to some extent, in ppm 17 value percentage some -- some DMAs. 18 So I don't see why there's any 19 conflict here. So I -- I don't see why I 20 should actually include this citing this 21 table because that's already be the fact 22 that by the time when they actually look 23 back. 24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 116</p> <p>1 topic, we have to know what we talk about, right? 2 So this is in 2018 when the whole 3 thing showed up. Everybody understand, including 4 myself now, right? So this reaction could 5 actually lead to this impurity. Nobody want that. 6 ZHP didn't want it. Nobody want that, but it 7 happen. 8 Now, when we look back to figure, 9 oh, what is the cause? Why this actually happen? 10 They did this whole bunch of analysis. 11 Actually, in my lab, we do this as 12 well, right? So we cannot design a project that 13 goes just like you design. Unfortunately, science 14 is not like that, right? 15 So happens a lot of time, if not all 16 the project, that at the end or on the way you 17 will find out the reaction didn't go like you will 18 happen, right? So you isolate and characterize 19 and find, okay, there is impurity, unfortunately, 20 formed. It's not something designed. It cost me 21 time and money, but we need to look back to see 22 how, what is the reason cause this. 23 So to do that, the general exercise 24 what I do, a lot of my colleagues, everybody in my</p>
<p style="text-align: right;">Page 115</p> <p>1 Q. My question is very simple. 2 Nowhere in your report do you talk 3 about the fact that ZHP did lab scale testing to 4 prove that the DMF could degrade, form DMA, and 5 then the sodium nitrite could combine with that to 6 create NDMA. 7 You don't discuss the fact that they 8 did those tests in your report, correct? 9 I'm not asking why you didn't do it. 10 I just want to confirm you didn't do it, right? 11 MR. BERNARDO: Objection. 12 THE WITNESS: Well, I do -- 13 MR. BERNARDO: Wait, wait, 14 wait, Dr. Xue. 15 Object to the form of the 16 question. Argumentative. 17 Go ahead, Dr. Xue. 18 BY MR. SLATER: 19 Q. I just want to know. Did I miss 20 it? Is it in your report or not? Just please. 21 It's a yes-or-no question. 22 A. You missed because it's a time 23 matter, right? It just like you run reaction, you 24 have to know the parameter. Here we discuss the</p>	<p style="text-align: right;">Page 117</p> <p>1 lab they also do is just to -- to see, okay, then 2 let's see what is a possible reason to cause this. 3 I believe this is what they did, right? 4 So, you know, I really don't see why 5 I should actually include this piece in there. So 6 what I want to prove? I don't see a point that 7 can actually bring to me, right? 8 We are not talk about, right, if you 9 tell me, okay, this is a table that ZHP or anybody 10 at ZHP they actually did in 20 -- in 2007 or 2010 11 even, right? So they know this already. That's 12 totally a different story, right? But we not talk 13 about that every. 14 I hope I address your question. 15 Q. Okay. Simple yes-or-no question. 16 Did you talk about ZHP's testing as 17 shown on page 9 of this deviation investigation 18 report in your report? Yes or no. 19 I just want to know if you talked 20 about it or not. 21 MR. BERNARDO: Dr. Xue, please 22 listen to Mr. Slater's question, right? 23 THE WITNESS: I didn't talk 24 about this experiment specifically in my</p>

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1 report.

2 BY MR. SLATER:

3 Q. In fact, you didn't talk about any

4 experiments performed by ZHP in your report,

5 correct?

6 A. So if I understand your question,

7 you are asking do I mention any experiments ZHP

8 performed in my report? That was your question,

9 right?

10 Q. Right. Yes-or-no question.

11 A. I mentioned everything. If you read

12 my report you said, right? I mention every

13 single, all four of their processes. Every step I

14 actually have joined all those reaction in my

15 report. I mention every reaction they perform,

16 how they do it, and what the conditions are. When

17 they actually make any change, what kind of

18 parameter they actually change they follow. They

19 perform all these testings. I mention that.

20 If you ask me whether these six

21 reaction you show in this table right now? I

22 didn't mention that. As I explain to you just

23 now, I don't see why I should mention that in my

24 report.

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1 Q. So if I understand your opinion, ZHP

2 proved after the fact that the DMF could degrade

3 to give off dimethylamine, but there's no way that

4 they would have known that before they developed

5 the process or while they used the process. So

6 they were never on notice that DMA might be

7 introduced to the zinc chloride process; is that

8 correct?

9 MR. BERNARDO: Object to the

10 form of the question and the

11 characterization of his testimony.

12 BY MR. SLATER:

13 Q. Is that your opinion?

14 MR. BERNARDO: Go ahead.

15 THE WITNESS: So I'm here

16 trying to address the -- the expert from

17 the plaintiff side, right?

18 So my opinion, I think, is

19 very clear I mention about these. They

20 have no -- they don't know and they have

21 not reasonably be able to expect to know

22 these are actually can trigger the issue.

23 BY MR. SLATER:

24 Q. Did ZHP consider the fact -- well,

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1 let me ask you this.

2 Did you consider -- I don't want to

3 do it that way, actually.

4 Did ZHP take into consideration

5 whether or not DMA, which is dimethylamine, could

6 be an impurity of commercially purchased DMF such

7 that they could introduce DMA into the zinc

8 chloride process as an impurity when they put the

9 DMF into the process? Did they consider that

10 possibility?

11 MR. BERNARDO: Object to the

12 form of the question. Compound.

13 Go ahead.

14 THE WITNESS: So now we are

15 changing to from formation from a

16 degradation to -- to you imply there's a

17 contamination already before they

18 actually perform the reaction in common

19 with the DMF? That what -- that's what

20 you refer to?

21 BY MR. SLATER:

22 Q. Did ZHP consider that possibility,

23 to your knowledge?

24 A. To my knowledge, I don't think they

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1 did.

2 Q. That's all I asked.

3 A. Thank you. I got one.

4 Q. In forming your opinions, did you

5 consider the possibility that DMA could have been

6 introduced to the zinc chloride process as an

7 impurity of the DMF?

8 A. You're asking me when I formed my

9 opinion whether I considered contamination of DMF

10 by DMA? You ask me about that? I just want to

11 confirm that's what the question you're asking.

12 Q. Yes. When you formed your opinion,

13 did you consider the possibility that DMA could be

14 an impurity of commercially purchased DMF and be

15 introduced to the zinc chloride process as an

16 impurity of the DMF?

17 A. Right.

18 Q. Did you consider that possibility?

19 A. Right. So when I --

20 Q. It's a yes-or-no question. I just

21 want to know if you considered that possibility or

22 not. Yes or no.

23 MR. BERNARDO: Objection.

24 THE WITNESS: When I formed

<p style="text-align: right;">Page 122</p> <p>1 my opinion, I mostly address what the --</p> <p>2 the expert from the plaintiff side,</p> <p>3 right? So I don't recall they actually</p> <p>4 raise this in their report. That's the</p> <p>5 reason why when I formed my opinion, I</p> <p>6 didn't really trying to include this</p> <p>7 section or this study, this discussion in</p> <p>8 my report.</p> <p>9 I think so far the only --</p> <p>10 because there's so many documents, right?</p> <p>11 But the only document that I can -- I can</p> <p>12 recall that -- that sort of addressed</p> <p>13 this was, I think during the root cause</p> <p>14 study, ZHP did some sort of analysis of</p> <p>15 the DMF solvent they use in their</p> <p>16 processes.</p> <p>17 They found the, you know --</p> <p>18 I'm not regulatory science, right,</p> <p>19 scientist, but I know they found the --</p> <p>20 the grade of the DMF they used was -- was</p> <p>21 good. So they didn't actually find high</p> <p>22 ppm. I believe both DMA and DEA was --</p> <p>23 was way below the bar. I don't</p> <p>24 remember -- recall the specific numbers.</p>	<p style="text-align: right;">Page 124</p> <p>1 know because I can -- I cannot have</p> <p>2 know -- any reason to know whether ZHP</p> <p>3 know by then.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. You don't know. That's fine. It's</p> <p>6 okay. Based on everything you read, you don't</p> <p>7 know. That's your answer. It's fine.</p> <p>8 A. Yeah, I hope I can offer something.</p> <p>9 That's why.</p> <p>10 MR. SLATER: Let's -- let's</p> <p>11 put this aside for a second and put up as</p> <p>12 exhibit -- what are we up to 6 or 7?</p> <p>13 All right. Let's put up as</p> <p>14 Exhibit 6 the World Health Organization</p> <p>15 publication from 2001 titled</p> <p>16 "N,N-Dimethylformamide."</p> <p>17 THE WITNESS: Are you putting</p> <p>18 it up?</p> <p>19 (Document marked for</p> <p>20 identification as Xue Exhibit 7.)</p> <p>21 BY MR. SLATER:</p> <p>22 Q. We're putting it into the thing so</p> <p>23 you can download it. We're going to put it on the</p> <p>24 screen. I'm going to show you one page.</p>
<p style="text-align: right;">Page 123</p> <p>1 So that's the only reason.</p> <p>2 That's the only avenues, and then I don't</p> <p>3 think any of -- I might be wrong, but I</p> <p>4 don't think I read any of the -- the</p> <p>5 report from the plaintiff side mention</p> <p>6 those. So I didn't just -- just went on</p> <p>7 to address that directly.</p> <p>8 So I disagree that they didn't</p> <p>9 do any study or they don't know.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. Did ZHP know that the DMF it was</p> <p>12 purchasing could have DMA as an impurity and that</p> <p>13 it could be introduced into the zinc chloride</p> <p>14 process as an impurity of the DMF?</p> <p>15 Did ZHP know that when they --</p> <p>16 A. Well, as I said --</p> <p>17 Q. -- developed and used that process?</p> <p>18 Yes or no.</p> <p>19 I just want to know. What do you</p> <p>20 know about that? Yes or no. Did they know?</p> <p>21 MR. BERNARDO: Object to the</p> <p>22 form of the question. Foundation.</p> <p>23 Go ahead.</p> <p>24 THE WITNESS: Well, I don't</p>	<p style="text-align: right;">Page 125</p> <p>1 So, first of all, are you familiar</p> <p>2 with this document? Have you seen this?</p> <p>3 A. I think I saw this before.</p> <p>4 Q. Okay. This would be scientifically</p> <p>5 knowable to somebody who was developing the zinc</p> <p>6 chloride process at ZHP, right?</p> <p>7 MR. BERNARDO: Object to the</p> <p>8 form of the question.</p> <p>9 BY MR. SLATER:</p> <p>10 Q. This document would be available to</p> <p>11 somebody who's a chemist at ZHP, right?</p> <p>12 A. Well, as you just described, the</p> <p>13 document is available. I don't know whether ZHP</p> <p>14 has read that or not. I cannot speak for other</p> <p>15 people. I read this before. It is available as</p> <p>16 you described.</p> <p>17 Q. Let's go to page 5.</p> <p>18 A. Okay. 5 of the document, right?</p> <p>19 Q. Yep. It's right there on the</p> <p>20 screen. Paragraph 2. Or not. Rephrase.</p> <p>21 Looking at page 5 of this</p> <p>22 publication, Section 2 titled "Identity and</p> <p>23 Physical/Chemical Properties" in the bottom,</p> <p>24 right.</p>

<p style="text-align: right;">Page 126</p> <p>1 Do you see that?</p> <p>2 It's on the screen, Doctor. It's</p> <p>3 right in front of you on the screen.</p> <p>4 Do you see it?</p> <p>5 A. Yeah. Yeah. Yeah. I mean, I'm</p> <p>6 sorry. I was looking at my -- my own trying to.</p> <p>7 Yeah, go ahead.</p> <p>8 Q. And there's a paragraph that talks</p> <p>9 about N,N-Dimethylformamide.</p> <p>10 Do you see that first paragraph?</p> <p>11 A. The second last paragraph from</p> <p>12 the -- on the right column, right?</p> <p>13 Q. Correct.</p> <p>14 A. Okay. I saw that.</p> <p>15 Q. The last sentence of that paragraph</p> <p>16 says:</p> <p>17 "DMF sold commercially contains</p> <p>18 trace amounts of methanol, water, formic acid, and</p> <p>19 dimethylamine." And there's a citation to 1994.</p> <p>20 Do you see what I just read?</p> <p>21 A. I saw what you just read.</p> <p>22 Q. Before I just showed you that, were</p> <p>23 you aware that DMF sold commercially contains</p> <p>24 trace amounts of methanol, water, formic acid, and</p>	<p style="text-align: right;">Page 128</p> <p>1 small molecules can actually present in DMF, I</p> <p>2 don't know.</p> <p>3 Q. Okay. In forming your opinions in</p> <p>4 this case --</p> <p>5 A. Right.</p> <p>6 Q. -- did you consider the fact that</p> <p>7 DMF sold commercially contains trace amounts of</p> <p>8 dimethylamine such that DMA -- well, let me stop</p> <p>9 there. Let me ask it again.</p> <p>10 When you formed your opinion in this</p> <p>11 case, did you take into account the fact that DMF</p> <p>12 sold commercially contains trace amounts of</p> <p>13 dimethylamine?</p> <p>14 MR. BERNARDO: Object to the</p> <p>15 form of the question. Compound. Asked</p> <p>16 and answered.</p> <p>17 Go ahead, Dr. Xue.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Just want to know if you considered</p> <p>20 that when you formed your opinions in this case.</p> <p>21 A. Well, when we buy or when we use any</p> <p>22 chemical in practice as a chemist, right? So you</p> <p>23 always rely on the -- on the certificate you got</p> <p>24 from the vendor, right?</p>
<p style="text-align: right;">Page 127</p> <p>1 dimethylamine? Did you know that before right</p> <p>2 now?</p> <p>3 A. Are you -- if you ask me</p> <p>4 specifically of these four substance -- methanol,</p> <p>5 water, formic acid, and dimethylamine -- do I know</p> <p>6 whether these are the four contamination that can</p> <p>7 possibly contains in the -- in the DMF sold</p> <p>8 commercially, I probably don't know the four off</p> <p>9 my head. But as a --</p> <p>10 Q. Did you know -- go ahead.</p> <p>11 A. Sorry. Can I -- can I go ahead?</p> <p>12 Yeah.</p> <p>13 But as an organic chemist, right, we</p> <p>14 buy solvents like DMF or other solvent all the</p> <p>15 time, right? So they always have a certificate</p> <p>16 come along with it. So that's where we actually</p> <p>17 go for it.</p> <p>18 We -- we usually, like my lab, if we</p> <p>19 want a 99.9 percent, so we actually trust what the</p> <p>20 vendor told us and we read the -- we call it a</p> <p>21 Safety Data Sheet to actually learn this</p> <p>22 information.</p> <p>23 But if you ask me whether I know</p> <p>24 this particular sentence or these four specific</p>	<p style="text-align: right;">Page 129</p> <p>1 So this sentence by reading says</p> <p>2 "sold commercially contains trace amount" these.</p> <p>3 First of all, trace amount is a very vague. Like</p> <p>4 1 ppm or .001 ppm of each, that should be listed</p> <p>5 specifically for each one of the chemicals that</p> <p>6 you order.</p> <p>7 So this is just, I think, is a</p> <p>8 summary from the WHO. That really does not tell</p> <p>9 you a specific product for me. Because if I'm</p> <p>10 doing my research running my reaction, if I want</p> <p>11 to buy something that I care, I have to go</p> <p>12 specifically to that website and downloading the</p> <p>13 corresponding data sheet or called Safety Data</p> <p>14 Sheet to -- to read what exactly in there.</p> <p>15 So I don't take for granted that</p> <p>16 this is the four compound that must be contained</p> <p>17 in my DMF and, again, trace is a very vague number</p> <p>18 they will not use.</p> <p>19 Q. Doctor.</p> <p>20 A. Yes.</p> <p>21 Q. When you formed your opinion, did</p> <p>22 you take into account the possibility that the DMA</p> <p>23 was introduced into the zinc chloride process as</p> <p>24 an impurity or contaminant of the commercially</p>

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1 purchased DMF that was used? Yes or no.
 2 A. I didn't because ZHP showed during
 3 their study their DMF doesn't contain
 4 dimethylamine.
 5 Q. Okay. Now, next question.
 6 You said that you worked --
 7 A. But can I -- can I -- can I say
 8 something, too?
 9 Q. I asked you -- see, here's the
 10 problem, Doctor. I asked a simple question. You
 11 answered it. I don't know why you want to talk
 12 about something else.
 13 I didn't ask why. I'm not asking
 14 for an explanation. I'm never going to finish
 15 this deposition if you give me long stories about
 16 things I'm not asking about.
 17 A. I did not. I just want to point out
 18 one thing. While you're on this document, I was
 19 on the second screen I saw something. Can I raise
 20 that?
 21 Q. No. I'm not asking about something
 22 on the second screen. I asked you a simple
 23 question that's not even about this document at
 24 this point.

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1 A. But you don't allow me to -- to
 2 raise that point? That's what you're saying?
 3 Q. I want an answer to my question, and
 4 you answered. You're not answering my question.
 5 My question -- let's take this down off the screen
 6 because I'm not even asking about this document.
 7 When you formed your opinions, did
 8 you take into account the possibility that the DMA
 9 was introduced to the zinc chloride process as a
 10 preexisting impurity or contaminant of the
 11 commercially purchased DMF that was used?
 12 You already said you did not take
 13 that into account, correct?
 14 A. I didn't. I said -- what I said --
 15 Q. That's all I asked. I just wanted
 16 to know if you took it --
 17 A. Can I explain?
 18 Q. -- into account, and you said no.
 19 A. Can I explain?
 20 Q. I understand why, but I don't -- I
 21 don't need an explanation. I'm going to go on to
 22 the next question now.
 23 A. No, that was not my -- my statement.
 24 That's not my testimony.

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1 I didn't consider, one, because ZHP
 2 did the root cause study to show that their DMF
 3 didn't contain, and they have a specific number
 4 listed. They are not -- they are below 10 ppm,
 5 but they didn't do any.
 6 And plus, as I already mentioned,
 7 the expert from the plaintiff side during their --
 8 during their -- in their opinions or in their
 9 writing the report, they didn't address this. So
 10 that's why I didn't put it in there. That's the
 11 only evidence I saw. So I didn't -- I didn't
 12 address that in my report.
 13 But you want me to -- to agree with
 14 you that, you know, I didn't consider this. I
 15 want to let you know the truth. That's what I --
 16 I actually put down.
 17 And just now before I can finish,
 18 you take down that PowerPoint or not -- that
 19 document. I think it's not quite fair because I
 20 really just now see something.
 21 I mean, it's actually the page right
 22 next to that page that says actually the
 23 temperatures in excess of 350 degrees C are
 24 required for DMF to decompose into carbon monoxide

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1 and dimethylamine. That's also on the same exact
 2 document that you just showed me. I think I have
 3 the right to point it out.
 4 So if we all agree, WHO is -- is out
 5 there and it's up there. Everybody should
 6 actually respect the WHO. So I think we need also
 7 think about WHO in their same document. If you
 8 put it up again on that -- on that file you just
 9 -- you just take down quickly.
 10 On page 6 of that document on the --
 11 on the left column on the top paragraph it says
 12 what I just read. "Temperatures in excess of 350
 13 degrees C." That's way, way above the condition
 14 that ZHP been using to perform their tetrazole
 15 formation reaction actually are required for DMF
 16 to decompose.
 17 So I want to -- I want to read that
 18 to you so you have a record. So that's something
 19 I want to point out.
 20 Q. You said something earlier.
 21 You said that you, as a -- as a
 22 chemist -- organic chemist, when you purchase
 23 substances, you look at the Material Safety Data
 24 Sheet.

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1 Remember you said that?

2 A. I usually do.

3 Q. Are you familiar what a Certificate

4 of Analysis is?

5 A. I don't know off my head what

6 Certificate of Analysis mean.

7 Q. One of the things you said is, as an

8 organic chemist, you should always rely on the

9 certificate from the vendor as to what is in the

10 substance you purchased, right?

11 A. We -- we -- if we need information

12 from there, like if I want to figure out the

13 decomposition of DMF if I buy it, I will just go

14 there to look. That's my -- that's my side. I

15 usually do. I'm not saying everybody else should

16 do the same. That's my practice. I teach my

17 student the same way.

18 Q. You would expect that the chemists

19 at ZHP looked at the Certificate of Analysis to

20 know the composition of the DMF they were

21 purchasing to put into the zinc chloride process,

22 right?

23 A. Well, I cannot speculate for any

24 other people than myself. I told you I do that.

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1 Q. You have no opinion on that?

2 A. Well, my opinion is I do that and my

3 student in my lab, they all do that because I

4 advise them to do so. I -- I cannot force other

5 people to do the same way as I do.

6 Q. Do you have an opinion as to whether

7 the chemists at ZHP should have looked at the

8 Certificate of Analysis for the DMF that they

9 purchased for use in the zinc chloride process?

10 I just want to know if you have an

11 opinion on that or not. If you, you do. If you

12 don't, you can say, "I don't have an opinion."

13 A. I don't know what other people do.

14 Q. Have you seen any Certificates of

15 Analysis or Material Safety Data Sheets regarding

16 the DMF or any of the other substances that were

17 used in the zinc chloride process or the TEA with

18 sodium nitrite quenching process?

19 A. You ask me if I went in to look at

20 the data sheet?

21 Q. I'm asking if that was provided to

22 you, if it's one of the materials you reviewed in

23 forming your opinions in this case.

24 A. Well, I --

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1 Q. Yes or no. Did you or not?

2 A. This is not a yes-or-no question.

3 Can you let me finish?

4 I told you early on, right, I was

5 provided a lot of document. I also did my own

6 research. So to go out to look for the data sheet

7 was my own practice. Nobody provide this to me,

8 and this is my routine exercise from -- for

9 anything that I do.

10 Q. Right.

11 Did you do that here?

12 A. I'm sorry. For which one?

13 Q. Did you -- did you do any research

14 to see what the Certificate of Analysis or the

15 Material Safety Data Sheet or any information from

16 the manufacturers of the DMF might have said about

17 the contents of the DMF that was purchased by ZHP?

18 Did you do any research on that?

19 Yes or no.

20 A. I did research myself to see what's

21 available for DMF from the site that I purchase

22 DMF. I don't know. I have no reason to know what

23 ZHP has been purchased from. So I --

24 Q. Is that -- is that in your reliance

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1 list? Did you list that you did that research and

2 what you found when you looked at your supplier's

3 website on DMF?

4 MR. BERNARDO: Object to the

5 form of the question. Vague.

6 BY MR. SLATER:

7 Q. I just want to know.

8 Did you disclose it in your report

9 or on your reliance list? Yes or no.

10 MR. BERNARDO: Object to

11 the --

12 THE WITNESS: My reliance list

13 has so many things. I disclose

14 everything that is provide to me from the

15 counsel. I disclose everything that I

16 use to form my opinion.

17 BY MR. SLATER:

18 Q. Did you disclose everything you

19 found --

20 A. If you push me to the corner --

21 Q. -- in your report?

22 A. Well, if you push me to the corner

23 like this to say what I disclose exactly let me

24 memorize at this moment everything, I don't think

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1 is fair.

2 Q. Doctor, I didn't ask you to disclose

3 everything to me right now.

4 I'm asking you. You just told me

5 you did research on the website of your DMF

6 supplier for your lab.

7 A. Right.

8 Q. Did you do that in connection with

9 this case?

10 A. I did search DMF.

11 Q. What did you find?

12 A. I'm sorry?

13 Q. What did you find?

14 A. I find a documentation that is

15 called a Safety Data Sheet for my DMF search. I

16 see the parameters that in there. I didn't look

17 at every detail, but I did find in there they also

18 mention the degradation temperature is 350

19 degrees C.

20 Q. Did they talk about in that document

21 the potential for impurities including

22 dimethylamine?

23 A. I don't remember those.

24 Q. You don't remember.

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1 Did you look at the Certificate of

2 Analysis for the contents of the DMF, which is

3 something that would be different from the

4 Material Safety Data Sheet? Did you look for that

5 document?

6 A. Honestly, I don't even know what the

7 document is. If you have example, if you put it

8 up, I will probably be --

9 Q. No.

10 A. -- report that.

11 Q. Okay. Where -- so you did research.

12 You looked at a website, and I just want to know.

13 Where is that listed in your report

14 or on your list of materials reviewed? Is that

15 listed anywhere?

16 The DMF supplier's website. I just

17 want to know. Is it listed in your report or your

18 reliance list?

19 A. Well, I --

20 Q. It's a yes-or-no question.

21 A. I don't know at this moment. I say

22 I never hide anything. If I consider everything,

23 I put in the report or put in the list of

24 consideration. I...

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1 Q. Okay.

2 A. I may use some as my citations, may

3 use others as citations. For that I choose, but I

4 didn't hide anything.

5 Q. Well, I didn't ask if you hid

6 anything. I just asked if you mentioned it or

7 listed it anywhere in your report.

8 A. Well, as I mentioned to you then, I

9 really off my head I don't recall all these

10 details. I hope you don't push me to do that.

11 Q. Let's look at -- let's go back to

12 the deviation investigation report.

13 A. Can you remind me the number again?

14 Q. It's Exhibit 5, sir.

15 A. Thank you so much.

16 Q. Go to page 157 of 236.

17 Looking at the bottom half of the

18 page.

19 A. Sorry. I'm -- I'm moving slower

20 than you.

21 Q. It's right on the screen. I mean,

22 you can see it. It's right on the screen.

23 A. I understand it's on the screen.

24 I'm sorry. I also want to see that report, the

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1 document on my own so I know what I'm reading. I

2 don't want to make any mistake.

3 Q. Scroll down a tiny bit just so we

4 can see the middle of the page also. No, the

5 other way.

6 A. Are you talking about page 153?

7 Q. 157.

8 A. Oh, 7.

9 Okay. 57 -- 157 of 236.

10 Q. All right. So looking right at the

11 middle of the page, it talks about "Discussion on

12 Suppliers of DMF" and there's "Supplier

13 Information."

14 Do you see that?

15 A. I can read there's supplier

16 information there.

17 Q. And the paragraph says:

18 "Huahai has written procedure 'API

19 Supplier Procedure of Raw Materials SMP-018.08' to

20 regulate the selection, examination, assessment,

21 evaluation and audit of suppliers. There had been

22 five suppliers of DMF (correspond to two

23 manufacturers) in Huahai since 2010. All of them

24 meet the requirements of the procedure by

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1 reviewing supplier information. The details are
 2 in Table 4-32 as follows."
 3 Do you see what I just read?
 4 A. Yes, I did see the section that you
 5 read.
 6 Q. And if you look at the table below,
 7 it lists the suppliers and the manufacturers of
 8 the DMF.
 9 Do you see that?
 10 A. I see there's a Table 3 columns,
 11 right? They talk about the suppliers,
 12 manufacturer, and the approval dates. Yes.
 13 Q. Okay. And you see one of the
 14 companies is Shandong Hualu Hengsheng Chemicals
 15 Company, Limited? Do you see that's one of the
 16 manufacturers of the DMF that was used by ZHP?
 17 A. I --
 18 Q. In the Manufacturer column, if you
 19 read the manufacturers' names, there's two
 20 manufacturers. One of them is Shandong Hualu
 21 Hengsheng Chemicals.
 22 Do you see them?
 23 A. You talk about the last one in the
 24 column. Is that the --

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1 Q. It's the column that -- there's a
 2 column that says "Manufacturer."
 3 Do you see the column?
 4 A. Right. I see within the column you
 5 talk about the last row.
 6 Q. Yes.
 7 A. Okay. Yeah.
 8 Q. If you go to the next page, you'll
 9 see they're also listed there, too, okay? But
 10 that's Shandong. I'm going to call them Shandong.
 11 Okay?
 12 A. So I --
 13 Q. Doctor, I don't know what we're
 14 doing. Let me -- let me do this.
 15 Do you see one of the manufacturers
 16 is Shandong Hualu --
 17 A. Yes.
 18 Q. -- Hengsheng Chemicals?
 19 A. I do. You also talk about next
 20 page, right?
 21 Q. Forget that. Forget it. I'm asking
 22 you to read that.
 23 A. Okay. Yeah.
 24 Q. You see Shandong is one of the

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1 manufacturers?
 2 A. Based on reading, that is. Yes.
 3 MR. SLATER: Okay. Let's put
 4 up the Shandong document now.
 5 I would -- I would like to --
 6 well, do you have it all as one document?
 7 Make it into one document and
 8 let's put it up. Put up whatever you
 9 have. I just want to move through this.
 10 I'd rather have done it as
 11 one, but we'll do it all. I just want to
 12 move through this.
 13 BY MR. SLATER:
 14 Q. What we did, Doctor, is we went on
 15 the Internet and we got the Certificate of
 16 Analysis for Shandong's DMF.
 17 And I'm just going to walk you
 18 through what we did.
 19 This is the website we went to.
 20 Okay? This is Shandong's website.
 21 A. I'm sorry. Are you talking about
 22 the PDF you're showing me now?
 23 Q. Yeah, this is Exhibit what?
 24 A. It's written in Japanese and

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1 English?
 2 Q. What I'm showing you is a website --
 3 hold on.
 4 All right, Doctor, we're going to
 5 cut to the chase here. We're going to put up on
 6 the screen. What exhibit number are we up to?
 7 A. Number --
 8 Q. I'm not asking you, Doctor. Sorry.
 9 A. Sorry.
 10 MR. SLATER: What exhibit is
 11 this?
 12 Okay. This is Exhibit 7.
 13 (Document marked for
 14 identification as Xue Exhibit 7.)
 15 MR. SLATER: Two pages?
 16 BY MR. SLATER:
 17 Q. Doctor, on the screen is Exhibit 7.
 18 It's a Certificate of Analysis that we obtained
 19 for Shandong's DMF.
 20 Do you see that on the screen?
 21 MR. BERNARDO: I'm just going
 22 to reserve my objection to this. I don't
 23 have a copy of it to look at yet, but
 24 just reserve. Go on.

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1 BY MR. SLATER:
 2 Q. Okay.
 3 A. Well, I can -- I can see the
 4 document. This, again, is also new to me. I
 5 haven't seen this document before.
 6 Q. Do you see that it has a list -- a
 7 list of specifications and results and shows that
 8 there's dimethylamine at 1 part per million in the
 9 DMF from Shandong?
 10 MR. BERNARDO: I object to the
 11 form of the question.
 12 And, Adam, can you just
 13 display so we all know what the date of
 14 this document is at least? I don't have
 15 a copy of it.
 16 MR. SLATER: I don't know the
 17 date of the document. I don't know what
 18 that is.
 19 MR. BERNARDO: You're asking
 20 the witness a question.
 21 MR. SLATER: Hey, I don't need
 22 to be laughed. Okay? So you want to do
 23 that, do that with somebody else.
 24 MR. BERNARDO: Okay. Adam,

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1 there's not an iota of laughter in what I
 2 said and you know that, and let's just --
 3 come on, Adam.
 4 MR. SLATER: I'm watching your
 5 face. I want to continue the deposition.
 6 You guys --
 7 MR. BERNARDO: I do, too, but
 8 don't comment and claim I'm laughing when
 9 I'm not.
 10 MR. SLATER: Hey, you're the
 11 one who asked my expert if he's seen the
 12 Certificates of Analysis for the DMF that
 13 to our knowledge was never produced by
 14 your client. Okay?
 15 MR. BERNARDO: Let's move on.
 16 MR. SLATER: Unless you want
 17 to make a representation that -- hey, do
 18 you want to tell us right now whether the
 19 Certificate of Analysis for the DMF were
 20 actually produced? Because our
 21 understanding is they weren't and we're
 22 not sure why.
 23 MR. BERNARDO: Okay. Let's
 24 move on and ask the witness.

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1 MR. SLATER: So the answer is
 2 you don't want to answer whether you
 3 actually produced them. So nobody
 4 else --
 5 MR. BERNARDO: So the answer
 6 is that I'm not being deposed here, Adam.
 7 I'm simply asking for the date of the
 8 document that we're all looking at on the
 9 screen so I understand what we're looking
 10 at.
 11 BY MR. SLATER:
 12 Q. I'm showing you a Certificate of
 13 Analysis from Shandong Hualu-Hengsheng Chemical
 14 Co. for dimethylformamide shows that it has
 15 dimethylamine --
 16 MR. BERNARDO: Objection.
 17 BY MR. SLATER:
 18 Q. -- consistent with that publication
 19 we showed you before saying that dimethylamine is
 20 an impurity of DMF.
 21 Do you see that on the screen?
 22 MR. BERNARDO: Object to the
 23 form of the question. Vague.
 24 THE WITNESS: I'm sorry.

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1 The -- the -- on my screen says "Internet
 2 unstable." I really didn't. I only hear
 3 you said "DMF" at the end. I didn't hear
 4 the question at all. Can you please
 5 repeat your question?
 6 BY MR. SLATER:
 7 Q. Do you see on the Certificate of
 8 Analysis it shows that the DMF contains
 9 dimethylamine?
 10 MR. BERNARDO: Object to the
 11 form of the question. Vague.
 12 THE WITNESS: On the table
 13 that you show me on this document, which
 14 I've never seen before, there is entry a
 15 couple dimethylamine ppm.
 16 BY MR. SLATER:
 17 Q. Do you agree with me that the
 18 chemists at ZHP should have been aware that DMA
 19 can be an impurity or a contaminant of the DMF
 20 that they were using? Should have been aware of
 21 that possibility? Should they have thought about
 22 that?
 23 MR. BERNARDO: Object to the
 24 form of the question. Vague. Assumes

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1 facts not in evidence.
 2 BY MR. SLATER:
 3 Q. Or do you have no opinion on that
 4 question?
 5 A. Well, first of all, this document,
 6 when did you get this document?
 7 Q. Doctor, I just asked you a question
 8 not about this document.
 9 A. Because this document is not very
 10 clear to me. So what --
 11 Q. Doctor, I didn't ask you about the
 12 document. So I'm not really sure why you're
 13 talking about it.
 14 Take it down.
 15 A. No. What date that you download
 16 this document. Is the document from --
 17 Q. The document was downloaded in the
 18 last few days.
 19 A. Okay. So -- so that means this is
 20 the --
 21 Q. You want to answer me? I don't know
 22 why you're talking to me about this because that's
 23 not what I asked you. I asked you a very direct
 24 question.

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1 A. I want -- I want to answer your
 2 question so that's why.
 3 Q. Okay. So let me ask it and you'll
 4 answer it. Okay?
 5 A. Okay.
 6 Q. Should the chemists at ZHP have
 7 considered the possibility that the DMF they were
 8 using in the zinc chloride process contained DMA?
 9 Yes or no.
 10 MR. BERNARDO: Object to the
 11 form of the question. Vague. Asked and
 12 answered.
 13 Go ahead.
 14 BY MR. SLATER:
 15 Q. Or you don't have an opinion.
 16 A. Well, as I just mentioned, right?
 17 So this, I need to know if you show a document.
 18 You said a few -- a few days ago this document is
 19 download from this website.
 20 I need to know whether this document
 21 is all the same document is also available when
 22 they actually purchased. You show me two
 23 documents, right? I just want trying to be
 24 scientific here.

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1 Q. You're not being scientific. You're
 2 being evasive.
 3 A. Well --
 4 MR. BERNARDO: Object to the
 5 form of the question. Let's stop with
 6 the characterizations here and arguments.
 7 MR. SLATER: I asked a very
 8 simple question.
 9 THE WITNESS: Can you let me
 10 finish?
 11 MR. SLATER: Maybe you can ask
 12 your witness to answer the question I
 13 asked.
 14 THE WITNESS: Can you please
 15 let me finish?
 16 MR. SLATER: It has nothing to
 17 do with the document.
 18 MR. BERNARDO: Let's --
 19 let's -- let's stop talking over each
 20 other. This is becoming harassing and
 21 I'm, like, let's just take a break and
 22 cool down because this is --
 23 MR. SLATER: No, we're not
 24 taking a break right now. I'm getting --

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1 I have a pending question. I want it
 2 answered.
 3 MR. BERNARDO: Answer the
 4 question and then we're going to take a
 5 break.
 6 BY MR. SLATER:
 7 Q. It's a very simple question, Doctor.
 8 A. Can I speak now?
 9 Q. No, you can't because I'm asking the
 10 question again.
 11 A. Right. So --
 12 Q. Can you answer it with a yes-or-no
 13 answer?
 14 A. I need to first understand the
 15 document and then I will answer the question.
 16 MR. BERNARDO: Dr. Xue, let --
 17 let -- let Mr. Slater ask his question.
 18 Forget about the document. Okay?
 19 BY MR. SLATER:
 20 Q. Should the chemists at ZHP have
 21 considered the possibility that the DMF that they
 22 were using in the zinc chloride process could
 23 contain DMA as an impurity or contaminant of the
 24 DMF? Yes or no, or you have no opinion.

<p style="text-align: right;">Page 154</p> <p>1 A. My opinion is they could, but as I</p> <p>2 said -- can I -- can I speak now?</p> <p>3 Q. I don't know what that means "they</p> <p>4 could."</p> <p>5 Is the answer, yes, they should have</p> <p>6 considered it, no, they shouldn't have, or you</p> <p>7 have no opinion?</p> <p>8 A. They should, but I --</p> <p>9 Q. You answered.</p> <p>10 A. Now, can I speak for myself?</p> <p>11 Q. I'd rather -- look, I can't stop you</p> <p>12 from talking, but you've answered my question.</p> <p>13 A. No.</p> <p>14 Q. No. You told me your opinion.</p> <p>15 A. You said the scope because every of</p> <p>16 my opinion has a scope, right?</p> <p>17 So you showed me one document first.</p> <p>18 On the document there shows this -- this company</p> <p>19 was a supplier for ZHP back to the year 2011 June,</p> <p>20 right?</p> <p>21 And then you showed me a second</p> <p>22 document where you told me you guys download a few</p> <p>23 days ago that shows what the -- the analysis or</p> <p>24 the data of the product of a few days ago, right?</p>	<p style="text-align: right;">Page 156</p> <p>1 the -- the same DMF actually have same kind of</p> <p>2 quality data sheet.</p> <p>3 Q. If the chemists at ZHP knew that DMA</p> <p>4 could be introduced to the zinc chloride process</p> <p>5 as an impurity of the DMF, they needed to take</p> <p>6 that into account when they did a risk assessment</p> <p>7 for the process, correct?</p> <p>8 MR. BERNARDO: Object to the</p> <p>9 form of the question. Calls for</p> <p>10 speculation.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Do you have an opinion, yes or no,</p> <p>13 or you don't have an opinion?</p> <p>14 A. So fact they don't know, right? I</p> <p>15 don't see any direct evidence to show that back</p> <p>16 then at the year 2011 they know. Because what you</p> <p>17 just show me is a website you show me three days</p> <p>18 ago, right? I don't know how many versions of the</p> <p>19 website has been evolved over the past decades. I</p> <p>20 really don't know. I cannot comment.</p> <p>21 And as I said multiple times earlier</p> <p>22 on, too, I'm here as an expert in organic</p> <p>23 chemistry trying to address what the expert from</p> <p>24 the plaintiff side actually raised as their</p>
<p style="text-align: right;">Page 155</p> <p>1 So now you want -- you want to ask</p> <p>2 me question about whether these two document can</p> <p>3 talk to each other. I can't because I have to</p> <p>4 understand and learn what is the specific</p> <p>5 situation you described to me. Okay?</p> <p>6 So, again, the company is supply --</p> <p>7 one of the suppliers back to 2011, and now you</p> <p>8 show me something that is they have a data sheet</p> <p>9 right now have this. I have no reason to</p> <p>10 speculate, but I don't know what their data sheet</p> <p>11 will be like at the year that you talk about</p> <p>12 they -- they serve as a supplier for -- for ZHP.</p> <p>13 So I, as the scientist, I have to be</p> <p>14 very clear about what I'm -- what I'm talking</p> <p>15 about. You talk about one thing over 10 years</p> <p>16 ago. Now you talk about this new discovery three</p> <p>17 days ago and you say -- you try to say this is the</p> <p>18 same thing.</p> <p>19 I can't really comment on that.</p> <p>20 That's why I was pausing. I need to actually</p> <p>21 really understand the situation that you describe.</p> <p>22 If you show me a document back to then or I don't</p> <p>23 even know whether this company would still be the</p> <p>24 best -- the supplier or they -- they actually have</p>	<p style="text-align: right;">Page 157</p> <p>1 comments, right?</p> <p>2 So in there, the four expert in</p> <p>3 their reports, I don't see them talk about</p> <p>4 contamination at all, or I don't remember any of</p> <p>5 the direct evidence to show that there is</p> <p>6 contamination. So I didn't go ahead to address</p> <p>7 that.</p> <p>8 So if there's no evidence to show</p> <p>9 that they have contamination in the report of the</p> <p>10 plaintiffs' expert, I really don't. You ask me</p> <p>11 about opinion back then this and that. Because my</p> <p>12 opinion was -- was trying to address what was</p> <p>13 offered from the plaintiff experts.</p> <p>14 If they have no trouble, they have</p> <p>15 no issue with it, I don't see why I should be here</p> <p>16 to address that.</p> <p>17 And at the end, the only evidence</p> <p>18 I've been aware is this root cause that ZHP did.</p> <p>19 They actually test their DMF, and it showed</p> <p>20 clearly with the data. So I'd like to see what</p> <p>21 exactly data we actually have on our table.</p> <p>22 The data was the DMF they tested</p> <p>23 was -- I think the dimethylamine was like 10 ppm,</p> <p>24 give or take. I might be wrong on the exact</p>

<p style="text-align: right;">Page 158</p> <p>1 number. And the dimethylamine was probably less 2 than 5 ppm. That's the data, right?</p> <p>3 So if we have the data and your 4 expert didn't raise any evidence to support that, 5 I just don't know what you expect from me.</p> <p>6 Q. I expect you to actually just answer 7 my questions and not give me a lecture, honestly.</p> <p>8 A. I'm sorry. I really don't intend to 9 give anybody lecture.</p> <p>10 Q. Because with all due respect, this 11 is your first time as an expert, and there may be 12 things that you're not aware of about your role or 13 what would be expected of you.</p> <p>14 A. I will learn over time.</p> <p>15 Q. You will, I'm sure. Just like we 16 all do.</p> <p>17 Did you see any Certificate of 18 Analysis in any document you saw from the 19 suppliers of the DMF to ZHP? Was that in any of 20 the documents you were provided? Did you see 21 that?</p> <p>22 A. I thought -- you called a lecture.</p> <p>23 I just I --</p> <p>24 Q. Just say yes or no or "I don't</p>	<p style="text-align: right;">Page 160</p> <p>1 And that definitely is a 2 factor that will take the -- the 3 challenge or that the puzzle to a 4 different level. Because now you know 5 there's this much DMF -- DMA actually 6 present in my solution.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. When you did your analysis of what 9 the chemists at ZHP should have done in your 10 report --</p> <p>11 A. Uh-huh.</p> <p>12 Q. -- were you evaluating whether or 13 not they should have been aware of potential 14 reactions and potential creation of impurities in 15 their process?</p> <p>16 A. I like your word "potential" because 17 that's our -- for myself in my career, that's 18 something really we address all the time as well.</p> <p>19 So as a scientist, we -- we do 20 that all the time, right? So potential side 21 reactions is definitely something we talk on daily 22 basis. Every project almost every reaction, 23 unfortunately, you always have something.</p> <p>24 So as a chemist, as you asking,</p>
<p style="text-align: right;">Page 159</p> <p>1 know." I mean, why -- why do I need a long 2 speech?</p> <p>3 Did you see a Certificate of 4 Analysis for the DMF from the manufacturer, 5 supplier, or not? I just want to know if you saw 6 one.</p> <p>7 MR. BERNARDO: Dr. Xue, if you 8 don't know or you don't recall, just tell 9 Mr. Slater you don't recall having seen 10 them.</p> <p>11 THE WITNESS: I don't -- I 12 don't recall seeing one.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. If you saw the Certificate of 15 Analysis for the DMF and it showed that there was 16 -- that there was DMA in the DMF, that would be 17 important, wouldn't it?</p> <p>18 MR. BERNARDO: Object to the 19 form of the question. Vague.</p> <p>20 THE WITNESS: You are 21 speculating, right? So you say if I saw 22 on the certificate that provide me DMF 23 contains -- I don't remember the 24 number -- that amount of DMA, right?</p>	<p style="text-align: right;">Page 161</p> <p>1 right? So, yes, I think that's very important to 2 actually understand or trying to figure out, 3 foresee things.</p> <p>4 But everything, unfortunately, has a 5 scope, right? So you have a project. You have 6 your idea. You have your thought based on what 7 you learn was made available to you. You can't -- 8 you can't actually try to foresee or predict 9 what -- what potential things out there I'm trying 10 to duck or get away from.</p> <p>11 But that's -- that's the reality, 12 right? So what's -- what's available big, bit 13 question, right? So you need to -- you need to 14 really try your best to optimize the scope that 15 you can be foresee things. But, unfortunately, as 16 scientists, we never do. We never do, especially 17 for chemistry, right?</p> <p>18 So people say chemistry is 19 experiment. Unless you have the experiment to 20 show, okay, this condition that will happen, 21 right? So it's hard. Although you can learn 22 through textbook, through -- through your advisor 23 and things, but there's really just those 24 potentials you cannot always predicting.</p>

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1 So you try the hardest try to -- to
2 actually help yourself, but, unfortunately, that's
3 not means you can -- you can foresee everything
4 out there.
5 Q. Are you aware of whether or not ZHP
6 was required to ensure that there were no
7 genotoxic impurities in the valsartan it was
8 manufacturing?
9 MR. BERNARDO: Object to the
10 form of the question.
11 THE WITNESS: Well, as I
12 said --
13 MR. BERNARDO: Wait. Dr. Xue,
14 hold on. Let me get my objection.
15 Object to the form of the
16 question. Beyond the scope of his expert
17 opinion. Compound.
18 Go on. You can answer,
19 Dr. Xue.
20 THE WITNESS: Well, the
21 Internet was not very stable.
22 But I'm not a regulatory
23 scientist. About these requirement or
24 regulatory science-related questions, I

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1 really not sure whether I'm the right
2 person to ask.
3 MR. BERNARDO: And, Adam, I'll
4 repeat. When we're at a breaking point.
5 We've been going an hour and a half.
6 MR. SLATER: We can do it
7 right now.
8 MR. BERNARDO: Okay. Great.
9 THE VIDEOGRAPHER: Going right
10 now.
11 MR. BERNARDO: I think the
12 logical time for a lunch break.
13 MR. SLATER: Fine. How long
14 do you want?
15 MR. BERNARDO: Dr. Xue, how
16 long --
17 THE VIDEOGRAPHER: The time is
18 12:54 p.m. We're off the record.
19 (Whereupon, at 12:54 p.m., a
20 luncheon recess was taken.)
21
22
23
24

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1 AFTERNOON SESSION
2 (1:33 p.m.)
3 FENGtian XUE, PHD
4 called for continued examination and, having been
5 previously duly sworn, was examined and testified
6 further as follows:
7 EXAMINATION (CONTINUED).
8 THE VIDEOGRAPHER: Time right
9 now is 1:33 p.m. We're back on the
10 record.
11 MR. SLATER: Okay. Let's put
12 up as Exhibit -- is it 8 that we're up
13 to?
14 We're going to put up an
15 article as Exhibit 8. Let's get it up
16 there.
17 (Document marked for
18 identification as Xue Exhibit 8.)
19 BY MR. SLATER:
20 Q. Now, Exhibit 8 is an article titled
21 "Dimethylformamide: Purification Tests For Purity
22 and Physical Properties" dated in 1977.
23 Do you see this?
24 A. Yes, I can see by your reading.

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1 That's correct.
2 Q. And we saw this on your supplemental
3 list of materials reviewed.
4 Do you recall reading this?
5 A. I -- I think so.
6 Q. And this is published by the
7 International Union of Pure and Applied Chemistry
8 in 1977.
9 Do you see that?
10 A. That is correct. 1977.
11 Q. Let's go -- obviously we don't have
12 -- let's go to page 887, please, and we'll go to
13 the top half of the page.
14 MR. SLATER: Can you blow that
15 up, please, Chris?
16 BY MR. SLATER:
17 Q. And if you go down almost halfway
18 down the page, after the first formula, there's a
19 sentence that starts with the word "Formic acid."
20 Do you see that?
21 A. Yes, I do see formic acid.
22 Q. It says:
23 "Formic acid and dimethylamine are
24 thus predominant impurities in DMF and determine

<p style="text-align: right;">Page 166</p> <p>1 the odor of the impure solvent."</p> <p>2 Do you see that?</p> <p>3 A. Yes, by reading. That's correct.</p> <p>4 Q. You would agree with me that the</p> <p>5 fact that DMF may contain DMA as an impurity was</p> <p>6 something that a chemist who was working with DMF</p> <p>7 in a manufacturing process for a drug product</p> <p>8 should have known, correct?</p> <p>9 MR. BERNARDO: Object to the</p> <p>10 form of the question.</p> <p>11 THE WITNESS: I disagree.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Let me ask you this question.</p> <p>14 Let's talk about what ZHP did with</p> <p>15 its processes, the TEA with sodium nitrite</p> <p>16 quenching and zinc chloride process.</p> <p>17 You're familiar with both processes,</p> <p>18 right?</p> <p>19 A. Yes.</p> <p>20 Q. And you're familiar with the fact</p> <p>21 that it was ZHP that developed those processes,</p> <p>22 correct?</p> <p>23 A. The process of TEA with quenching</p> <p>24 and zinc chloride was -- for manufacture was</p>	<p style="text-align: right;">Page 168</p> <p>1 develop their own.</p> <p>2 Q. Did the TEA process with sodium</p> <p>3 nitrite quenching -- was that something that was</p> <p>4 in use before ZHP started using it? That</p> <p>5 integrated process, did that exist before ZHP used</p> <p>6 it?</p> <p>7 A. Maybe I didn't make myself clear.</p> <p>8 So the chemistry part are known, but</p> <p>9 both ZHP -- TEA with quenching process or the zinc</p> <p>10 chloride process. But for in term of API</p> <p>11 synthesis using those chemistry, I think ZHP, they</p> <p>12 actually patent those.</p> <p>13 Q. When ZHP created those processes,</p> <p>14 they knew that they were going to introduce</p> <p>15 chemicals and solvents and various substances into</p> <p>16 the process, right?</p> <p>17 A. Yes. When they actually develop</p> <p>18 these process, they knew they're going to use</p> <p>19 reagents and solvent and patent everything in the</p> <p>20 process.</p> <p>21 Q. And do you agree that responsible</p> <p>22 chemists under those circumstances would need to</p> <p>23 understand the potential risks of introducing</p> <p>24 those various chemicals and substances and</p>
<p style="text-align: right;">Page 167</p> <p>1 developed by ZHP, but the chemistry part was not</p> <p>2 developed by ZHP because there are -- these</p> <p>3 reactions have been out there before they actually</p> <p>4 used in their projects.</p> <p>5 Q. The manufacturing processes that</p> <p>6 were titled the TEA with -- jeez. Let me start</p> <p>7 over.</p> <p>8 What -- what do you mean by what you</p> <p>9 just said when you -- when you provided that --</p> <p>10 A. Well, like in --</p> <p>11 Q. -- explanation at the end? I don't</p> <p>12 understand.</p> <p>13 A. -- my lab -- my lab develop a</p> <p>14 reaction, I publish this reaction or I patent this</p> <p>15 reaction. And then you if you own a lab, you can</p> <p>16 actually use my reaction published to develop your</p> <p>17 own process. You can use mine.</p> <p>18 So ZHP for their TEA process or the</p> <p>19 zinc chloride process, all these particular</p> <p>20 reactions in their process was not invented by</p> <p>21 them or developed by them. They are there before</p> <p>22 these two processes are -- are established.</p> <p>23 They use other people's work and</p> <p>24 develop their own. They use other people's to</p>	<p style="text-align: right;">Page 169</p> <p>1 reactions? Do you agree that they needed to</p> <p>2 understand the risks of doing that?</p> <p>3 MR. BERNARDO: Object to the</p> <p>4 form of the question. Vague.</p> <p>5 THE WITNESS: Right. For</p> <p>6 these particular processes, right, when</p> <p>7 you have API of valsartan in your mind,</p> <p>8 you have these organic we call it</p> <p>9 reaction of scheme.</p> <p>10 So those are designed and then</p> <p>11 they should actually know. Everybody</p> <p>12 when they actually develop something,</p> <p>13 they will based on their knowledge need</p> <p>14 to know what are the risks, and then they</p> <p>15 will try to avoid those risks.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. And they had to take into account</p> <p>18 that what they were manufacturing was going to be</p> <p>19 placed into a medication that people were going to</p> <p>20 take and put in their bodies, right?</p> <p>21 That was the purpose of what they</p> <p>22 were manufacturing was to create drugs to put in</p> <p>23 people's bodies, right?</p> <p>24 A. Manufacturer, yes. The ultimate</p>

<p style="text-align: right;">Page 170</p> <p>1 goal is definitely to -- to make drugs and people 2 can take. 3 I don't -- because what was the 4 question? So what's their responsibility about 5 what were you asking? 6 Q. It was a simple question. 7 When the -- when they were -- 8 rephrase. 9 The chemists who were involved in -- 10 A. Uh-huh. 11 Q. -- these processes had to understand 12 that what they were manufacturing was intended to 13 be placed into pills that were going to go into 14 the human body, correct? 15 A. Yeah. So the -- the manufacturing 16 chemist, as you mention, right, they -- they -- 17 they should be very clear of the ultimate goal of 18 their work will be eventually become pills for 19 patients. 20 Q. And you would agree that with regard 21 to the various substances -- well, rephrase. 22 When ZHP changed -- well, rephrase. 23 You understand that ZHP had four 24 different processes to manufacture valsartan over</p>	<p style="text-align: right;">Page 172</p> <p>1 no reason to form nitrosamines. 2 Q. When they developed the TEA with 3 sodium nitrite quenching process, that process has 4 the potential to create nitrosamines, correct? 5 A. As you asked for now, it's a fact. 6 This process did already produce nitrosamine. 7 Q. If -- 8 A. So everybody knows now. Sorry. 9 Q. If there was no sodium nitrite or 10 other pathway to create -- to injecting a 11 nitrosating agent into the process, there would be 12 no risk of creating a nitrosamine, correct? 13 A. Well, nitrosamine is formed from two 14 parts, right? You have, like you said, a 15 nitrosating agent in different forms that, and 16 then you also have to have a secondary amine 17 there. So these two must be there to form 18 nitrosamine. So if you remove one of the two, 19 then nitrosamine will not formed, at least based 20 on my knowledge. 21 Q. And with regard to the zinc chloride 22 process, the same would hold true. Without the 23 sodium nitrite that was part of the process, there 24 would be no potential to create a nitrosamine,</p>
<p style="text-align: right;">Page 171</p> <p>1 the course of time. You're aware of that, right? 2 The Tin Process, the TEA process, 3 the sodium nitrite quenching process, and the zinc 4 chloride process, right? 5 A. That's -- that's correct. 6 Q. The original process, the Tin 7 Process, you looked at the chemistry of that 8 process, right? 9 A. Yes, I did look into the chemistry 10 of the Tin Process. 11 Q. And based on your review, there were 12 no reactions that are in that process capable of 13 creating a nitrosamine, correct? 14 A. Right. If you ask me now when I -- 15 when I look at this based on my -- my knowledge 16 now, there's no chance for nitrosamine formation 17 based on my knowledge now. I mean, in the future 18 if we discover, that's -- that's -- that's a 19 different story. But now, no. 20 Q. And the same would hold true for the 21 TEA process, the first TEA process, before they 22 had sodium nitrite quenching, correct? 23 A. Yeah, with the scope of the 24 knowledge that I have, there's no -- no -- there's</p>	<p style="text-align: right;">Page 173</p> <p>1 correct? 2 A. Similar to what I said. You need 3 two parts to form a nitrosamine. If -- if you 4 don't, if you cut two -- one of the two parts, 5 either one of the two, then you will not have a 6 chance, based on what I learned. 7 Q. In terms of understanding potential 8 risks, when ZHP chose to introduce sodium nitrite 9 into the quenching process, they needed to 10 understand that if that was exposed to a secondary 11 amine, that could create a nitrosamine, correct? 12 The chemists at least need to have 13 that understanding at the basic level who were 14 creating this process, right? 15 A. I disagree. I think -- 16 Q. So you disagree. That's fine. I 17 just asked if you agree or disagree. I didn't ask 18 you why. 19 A. Okay. 20 Q. Were the chemists who decided to 21 introduce sodium nitrite into the sodium 22 nitrite -- rephrase. 23 The chemists who determined to 24 introduce sodium nitrite quenching into the TEA</p>

<p style="text-align: right;">Page 174</p> <p>1 process, as well as into the zinc chloride</p> <p>2 process, were they responsible to understand the</p> <p>3 risks of using sodium nitrite in that process?</p> <p>4 MR. BERNARDO: Object to the</p> <p>5 form of the question. Vague.</p> <p>6 THE WITNESS: You are asking</p> <p>7 me if the chemists who introduce sodium</p> <p>8 nitrite into the quenching process of</p> <p>9 either the zinc chloride or the TEA with</p> <p>10 quenching process will be responsible for</p> <p>11 the formation of nitrosamine. That was</p> <p>12 your question?</p> <p>13 BY MR. SLATER:</p> <p>14 Q. No. My question is: When ZHP --</p> <p>15 well, rephrase.</p> <p>16 When the chemists decided to</p> <p>17 introduce sodium nitrite to quench the sodium</p> <p>18 azide, they needed to evaluate the risks of using</p> <p>19 sodium nitrite in that process.</p> <p>20 You would agree that was something</p> <p>21 they had to assess and evaluate, right?</p> <p>22 MR. BERNARDO: Object to the</p> <p>23 form of the question. Vague.</p> <p>24 THE WITNESS: So when they</p>	<p style="text-align: right;">Page 176</p> <p>1 want to use as you introduce as a</p> <p>2 quenching reagent, you want to quench the</p> <p>3 excess of amount of azide.</p> <p>4 And then they want to also</p> <p>5 have a way to track it down to see where</p> <p>6 it ends, right, so you will know where</p> <p>7 whether this sodium nitrite they actually</p> <p>8 introduce will be enough in the final</p> <p>9 product of things.</p> <p>10 So that's I think something a</p> <p>11 chemist who actually develop this process</p> <p>12 should know.</p> <p>13 In term of whether they would</p> <p>14 be aware this sodium nitrite can become a</p> <p>15 nitrosating reagent, I disagree. I think</p> <p>16 that's something you're not easily aware.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Do you have any understanding of the</p> <p>19 level of scientific analysis that the people</p> <p>20 working at ZHP were required to conduct based on</p> <p>21 the regulations and the standard operating</p> <p>22 procedures that applied to them?</p> <p>23 MR. BERNARDO: Again, object.</p> <p>24 Dr. Xue is not being offered as a</p>
<p style="text-align: right;">Page 175</p> <p>1 actually introduce any reagent to a</p> <p>2 process to any of the reactions, they</p> <p>3 need to know what they add, right? And</p> <p>4 also they need to track it down to know</p> <p>5 where this component ends.</p> <p>6 So that -- if that's the</p> <p>7 question, the question is yes. So you</p> <p>8 should be able to or you should actually</p> <p>9 track it down and know where the chemical</p> <p>10 add, where it is.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. And they need to research to</p> <p>13 understand the potential risks of using sodium</p> <p>14 nitrite in that process. They needed to</p> <p>15 understand what are the potential risks of</p> <p>16 introducing this to the process.</p> <p>17 That's the responsible thing to do,</p> <p>18 right?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question. Vague. Compound.</p> <p>21 THE WITNESS: Well, when --</p> <p>22 when we introduce any reagent like sodium</p> <p>23 nitrite, so you need to know what you</p> <p>24 want to use this for, right? So that</p>	<p style="text-align: right;">Page 177</p> <p>1 regulatory expert.</p> <p>2 If you can answer it, go</p> <p>3 ahead.</p> <p>4 THE WITNESS: Yeah, it's out</p> <p>5 of my expertise. I cannot comment on</p> <p>6 that.</p> <p>7 BY MR. SLATER:</p> <p>8 Q. So you don't have an opinion as to</p> <p>9 the extent of scientific research that was</p> <p>10 expected of the chemists at ZHP in connection with</p> <p>11 the development and use of the zinc chloride and</p> <p>12 sodium nitrite quenching TEA processes?</p> <p>13 MR. BERNARDO: Object to the</p> <p>14 form of the question. Mischaracterizes</p> <p>15 his prior testimony.</p> <p>16 THE WITNESS: I do have</p> <p>17 opinion on that.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Okay. So you do have an opinion as</p> <p>20 to what extent of scientific research was required</p> <p>21 of the chemists at ZHP --</p> <p>22 A. Well --</p> <p>23 Q. -- by as a matter of the regulations</p> <p>24 and FDA guidances and internal SOPs that applied</p>

<p style="text-align: right;">Page 178</p> <p>1 to them?</p> <p>2 Do you have an understanding of that</p> <p>3 and an opinion as an expert?</p> <p>4 MR. BERNARDO: Object to the</p> <p>5 form of the question and the</p> <p>6 characterization of his prior testimony.</p> <p>7 THE WITNESS: I can't comment</p> <p>8 on regulatory science, but I said I have</p> <p>9 opinion on ZHP had within their scope of</p> <p>10 knowledge their -- their task a risk</p> <p>11 assessment in term of chemistry to</p> <p>12 actually before they actually make any</p> <p>13 change.</p> <p>14 Because as you said, there --</p> <p>15 there are four different processes they</p> <p>16 do. So each one of the change, they have</p> <p>17 done multistep analysis for their</p> <p>18 reactions each one of them to do those</p> <p>19 analysis.</p> <p>20 BY MR. SLATER:</p> <p>21 Q. Were the chemists at ZHP obligated</p> <p>22 to determine whether the changes to the</p> <p>23 manufacturing processes could introduce genotoxic</p> <p>24 impurities to those processes?</p>	<p style="text-align: right;">Page 180</p> <p>1 DNA modifiers actually are the biggest</p> <p>2 drug on the market. They treat cancer,</p> <p>3 right? So those are by some sort of</p> <p>4 definition can be quantified -- qualified</p> <p>5 as genotoxic. But they are actually out</p> <p>6 there for -- for patient treatment,</p> <p>7 right?</p> <p>8 So disease or even -- even the</p> <p>9 dosage format matters, too. Because some</p> <p>10 drug at a low dose, they can be helpful</p> <p>11 for -- for disease.</p> <p>12 So like, for instance, if you</p> <p>13 treat people with, you know, with</p> <p>14 infections antibiotics, some of the</p> <p>15 nitrous oxide-released molecules can</p> <p>16 be -- can be drugs, but when you have a</p> <p>17 high dose, they are actually can be</p> <p>18 toxic. They cause cancer sometimes.</p> <p>19 So it really depends on who</p> <p>20 you actually talk about, what the patient</p> <p>21 you talk about, what disease you talk</p> <p>22 about, what dose level you talk about.</p> <p>23 Yeah. So, again, I'm not a</p> <p>24 regulatory science scientist. I cannot</p>
<p style="text-align: right;">Page 179</p> <p>1 MR. BERNARDO: Object to the</p> <p>2 form of the question. Vague.</p> <p>3 THE WITNESS: So genotoxic</p> <p>4 impurities itself is a pretty broad</p> <p>5 concept. So can you be more specific</p> <p>6 like what we talk about here?</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Do you have any understanding as to</p> <p>9 whether or not, or to what extent, ZHP was</p> <p>10 required to evaluate these manufacturing processes</p> <p>11 for the potential creation of genotoxic</p> <p>12 impurities?</p> <p>13 MR. BERNARDO: Object to the</p> <p>14 form of the question. Vague.</p> <p>15 THE WITNESS: Well, although</p> <p>16 I'm not -- as I said, I'm not a</p> <p>17 regulatory science expert, but I know</p> <p>18 that genotoxic species is very broad</p> <p>19 topic. It's actually, you know, these</p> <p>20 toxic definition is also very vague. It</p> <p>21 depends on what disease you talk about.</p> <p>22 Like some of the disease, you</p> <p>23 know, toxic molecule may not be too bad.</p> <p>24 Like I do cancer research. Some of the</p>	<p style="text-align: right;">Page 181</p> <p>1 really tell you what are the required --</p> <p>2 requirements are for -- for ZHP chemist</p> <p>3 to actually know about.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. In the context of the processes to</p> <p>6 manufacture valsartan -- which is not a cancer</p> <p>7 drug, right?</p> <p>8 A. It's -- it's for high blood</p> <p>9 pressures.</p> <p>10 Q. In the context of the processes that</p> <p>11 we're talking about, the TEA with sodium nitrite</p> <p>12 quenching and the zinc chloride process --</p> <p>13 A. Right.</p> <p>14 Q. -- what level of scientific analysis</p> <p>15 was required of ZHP in order to investigate the</p> <p>16 potential for the creation of genotoxic impurities</p> <p>17 in those processes?</p> <p>18 Do you have any understanding of</p> <p>19 what level of scientific research was required?</p> <p>20 MR. BERNARDO: Object to the</p> <p>21 form of the question.</p> <p>22 THE WITNESS: For the level</p> <p>23 of requirement for scientific research, I</p> <p>24 didn't read much, but I read the -- the</p>

<p style="text-align: right;">Page 182</p> <p>1 FDA's announcement about these particular 2 potential genotoxic compound. They were 3 saying either NDMA from the zinc chloride 4 process or the NDEA from the TEA with 5 quenching process, they are just 6 possible, probable cancer-causing 7 reagent. 8 I remember FDA also highlight 9 in their announcement that even for the 10 patient with the highest dose of these 11 drugs, valsartan I think is over 300 12 milligram per -- per day for 4 years of 13 full treatment. Like they were saying, 14 if you have 8,000 something like that 15 patient, you possibly can have one 16 additional patient with cancer. So 17 that's -- that's how small the chance 18 will be. 19 So, again, I'm not a 20 regulatory science scientist, but I just 21 feel this is not -- well, that's the fact 22 that I read from -- from the FDA website. 23 BY MR. SLATER: 24 Q. Thank you but not what I asked you.</p>	<p style="text-align: right;">Page 184</p> <p>1 "Owing to its various modes of 2 degradation (hydrolysis, thermal and photochemical 3 decomposition) the principal impurities found in 4 DMF are: dimethylamine" and then it lists some 5 others. 6 Do you see that? 7 A. I do see that. 8 Q. First of all, you agree with me that 9 degradation of dimethylformamide can be caused 10 by -- by thermal cause, right? That's by 11 temperature, correct? 12 A. By reading that, that's what they 13 talk about. 14 Q. Well, you agree that's accurate, 15 right? 16 A. Where now we all learn that that 17 could actually happen. 18 Q. Well, this is -- this was published 19 in 1977. 20 So people knew in 1977 that DMF 21 could be degraded by temperature, right? 22 A. By reading that, that -- that is 23 what the author said. 24 Q. It was also known that DMF could be</p>
<p style="text-align: right;">Page 183</p> <p>1 Do you have an opinion as to the 2 level or extent of scientific research that ZHP 3 was required to conduct when it was developing 4 these processes in order to determine whether 5 there was a potential for the creation of 6 genotoxic impurities through these new processes 7 that they created? Yes or no. 8 A. I don't know the requirement because 9 I'm really not a regulatory scientist. I don't 10 know what the requirement ZHP had -- ZHP has to 11 follow to perform their research. 12 Q. Let's go within that document to 13 page 890, Exhibit 8. The article on 14 dimethylformamide from the International Union of 15 Pure and Applied Chemistry. Very top it says 16 "Tests For Purity." 17 Do you see that? 18 A. Yes. 19 Can you make it bigger, please? 20 Thank you. 21 Q. It's too big. 22 A. No, that's okay. Thank you. 23 Q. Okay. At the top of page 890, it 24 says "Tests For Purity."</p>	<p style="text-align: right;">Page 185</p> <p>1 degraded by hydrolysis, correct? 2 A. Yes, by reading, that's also there, 3 too. 4 Q. That's also a true statement in 5 chemistry, right? That DMF can be degraded by 6 hydrolysis, right? 7 A. That's the authors -- what the 8 authors wrote there. That's correct. 9 Q. Do you disagree? 10 A. Well, as a chemist, I always have to 11 be very specific with the conditions, right? So 12 like hydrolysis is -- it's a type of reactions, 13 right? Thermal or photochemical decomposition 14 also covers a whole spectrum of conditions. 15 So I -- you know, by saying this it 16 just say you're eventually you're going to die, 17 right? So that -- that is too vague as a 18 condition that is given. Because I'm not against 19 this. What I'm saying is by saying what I'm 20 saying here is really, it doesn't tell me what 21 condition the author is trying to actually 22 describe. 23 Q. What does hydrolysis mean? 24 A. Hydrolysis means when you have a</p>

<p style="text-align: right;">Page 186</p> <p>1 substance in the presence of water, the water can 2 actually attack the substance so that you can 3 actually form a product from water attacking. 4 Q. Okay. And you'll agree with me that 5 under certain circumstances -- I don't want to go 6 through a whole dissertation on it -- but under 7 certain circumstances, it's known and was known as 8 of at least 1977 that DMF could be degraded by 9 hydrolysis, correct? 10 A. Well, that's what the author said. 11 As -- as I just explained to you, hydrolysis is a 12 very broad type of reaction condition. They can 13 be actually happening in acidic or basic or 14 neutral conditions, or having other additives add 15 in there, too. Hydrolysis normally coupled with a 16 specific temperature as well as their 17 concentration. 18 So, yeah. So this is just describe 19 a very general broad type of reaction. That 20 doesn't tell me what specific condition, you know, 21 it will be used. 22 So, in other words, by just reading 23 this, I saw, okay, there's these authors claim 24 that potentials. But I won't know, for instance,</p>	<p style="text-align: right;">Page 188</p> <p>1 that you -- you will have a goal. You have 2 established a hypothesis that you reach out to see 3 something that is happening. 4 But I always say, if I don't know 5 what could happen, and then I would not probably 6 not establish an experiment and try to prove 7 something that I didn't expect. 8 So I hope I explain this like clear. 9 So you have to first have a goal, and then you 10 design something to achieve the goal. 11 Q. When it was decided by ZHP to use 12 DMF, if they had done research -- which we know 13 they didn't -- into the possible degradation or 14 impurities of DMF, they would have been able to 15 find literature like what I'm showing you right 16 now to know that under certain circumstances DMF 17 could introduce DMA into a process. 18 They would have at least known that 19 as a general point if they had done the research, 20 right? 21 A. If they done the research, they read 22 this paper. If I'm the person at ZHP, I do this. 23 I look at this. I say, oh, under hydrolysis, 24 which means in the presence of water. So that's a</p>
<p style="text-align: right;">Page 187</p> <p>1 what temperature will cause this or what kind of 2 concentration will cause this or how much acid or 3 base it will require to cause this. 4 Q. The best way to know if a certain 5 manufacturing process will cause degradation of 6 DMF would be to run a test, right? Run a test 7 under the circumstances under which the process is 8 going to be run and see what happens. 9 If you really want to know if that 10 process can cause that reaction, you can do a 11 test, right? That's -- that's something that you 12 can do, right? 13 A. Well -- 14 Q. Yes or no. Can you run a test? 15 A. You can run a test, but that's under 16 assumption that you know what could happen. 17 So it's like all research I do is we 18 call it hypothesis-driven, right? So you have a 19 idea. You thought something could happen. Then 20 you go out to establish a chemistry or a reaction 21 or a procedure trying to test that. But that's 22 how you make your steps. You move your chemistry 23 or you make your science forward. 24 So, you know, it's very, very common</p>	<p style="text-align: right;">Page 189</p> <p>1 very general situation. Or you have a thermal or 2 a photo. None of these are actually giving me any 3 direct evidence about what is really required. 4 This is basically telling me all the 5 environment, right? 6 Q. Right. 7 A. So we have moistures are run. We 8 have, you know, you have some sort of temperature 9 run. You always have light in the lab unless you 10 have a dark room. 11 So these are to me, yes, they are 12 statement, right? They are -- they are published. 13 They are available. ZHP, they do analysis. They 14 definitely have a chance to read this paper. They 15 can actually come to this paragraph to -- to read 16 this statement in particular. 17 But I put myself at that -- their 18 situation. If I read this, it won't actually help 19 me to understand a lot. 20 Excuse me. Sorry. 21 Q. It's okay. 22 If ZHP wanted to do a thorough risk 23 assessment for the introduction of DMF and to know 24 whether or not DMA would be created or be</p>

<p style="text-align: right;">Page 190</p> <p>1 introduced into the process, there were certain 2 tests they could have done, and I showed you in 3 the deviation investigation report they did tests. 4 Those could have all been done in 5 the beginning if they had chosen to do them, 6 correct?</p> <p>7 MR. BERNARDO: Object to the 8 form of the question. Compound. Vague.</p> <p>9 THE WITNESS: The situation 10 is, if they know. Like we are discussing 11 now. Yes, they -- they actually have a 12 method as you've shown, right? If they, 13 you know, they can do the test.</p> <p>14 But the problem for -- for us 15 is back to 2012 or '13 when they are 16 trying to develop these new processes 17 back then. They don't know that and, you 18 know, the very little information around 19 there -- not saying there's nothing, 20 right? So you shown me multiple 21 documents already.</p> <p>22 They are not -- to my opinion, 23 they are not give ZHP the hint that they 24 are potentially have trouble of</p>	<p style="text-align: right;">Page 192</p> <p>1 Which one is it: The general 2 chemist walking down the street or the chemist 3 who's actually developing a drug manufacturing 4 process and making choices as to what chemicals to 5 introduce to that process?</p> <p>6 I just want to know. Is it A or B?</p> <p>7 A. I cannot speak for that, really. 8 I'm a chemist. I view myself as the expert in 9 organic chemistry, but just now when I speak, I 10 really view I myself as an average chemist.</p> <p>11 I myself will not be aware of that. 12 So I don't say I'm much better than the people at 13 ZHP. They need to actually develop a process for 14 drug purpose. I fully respect that. They are -- 15 they are smart. They are high-level chemists.</p> <p>16 Excuse me.</p> <p>17 But the same time I say myself, if I 18 put myself at that -- their shoes, I won't be able 19 to.</p> <p>20 Q. Did you read in evaluating -- 21 rephrase.</p> <p>22 When you went through the factual 23 information to form your opinions -- 24 A. Uh-huh.</p>
<p style="text-align: right;">Page 191</p> <p>1 generating dimethylamine. I was just not 2 seeing that myself.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Well, I've shown you literature and 5 I could keep showing it to you indicating, 6 number one, that it was known that DMA was a known 7 impurity of commercially sold DMF.</p> <p>8 That was something that ZHP could 9 have easily known, right?</p> <p>10 A. I disagree.</p> <p>11 Q. Okay. You disagree. Okay.</p> <p>12 A. This -- even this moment I don't 13 think, right? So average chemist can -- can 14 easily know --</p> <p>15 Q. Yeah.</p> <p>16 A. -- that there -- there in their -- 17 in their DMF they have DMA.</p> <p>18 Q. Is the standard you're applying for 19 your opinions what the average chemist in the 20 world would know, or is the standard what a 21 process chemist working at a drug manufacturer 22 who's creating a process to manufacture a drug 23 that's going to go into the human body, which is a 24 regulated area, is that the standard?</p>	<p style="text-align: right;">Page 193</p> <p>1 Q. -- did you see anywhere where ZHP 2 said that the DMA could have been introduced both 3 through degradation of the DMF or as an impurity 4 of the DMF? Did you see whether -- what ZHP said 5 on that topic?</p> <p>6 MR. BERNARDO: Object to the 7 form of the question. Vague.</p> <p>8 THE WITNESS: As far as I 9 remember, when I reviewed the material to 10 form my opinion, I didn't see ZHP talk 11 about introduction of DMA. Because they 12 just don't even know that.</p> <p>13 But as you show me this 14 morning, when they do this call deviation 15 study or the -- the root cause study when 16 they know in their process, 17 unfortunately, this particular compound 18 was formed, they did go back to actually 19 try to figure out what was the cause of 20 how it's actually formed.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. And when you looked at that 23 analysis, did you see that ZHP concluded that the 24 DMA could have been introduced both as an impurity</p>

<p style="text-align: right;">Page 194</p> <p>1 of the DMF and/or as a degradation product of the</p> <p>2 DMF during the process?</p> <p>3 Did you see that in the deviation</p> <p>4 investigation report? Did you -- I just want to</p> <p>5 know if you saw that.</p> <p>6 A. Off my head, I honestly I cannot say</p> <p>7 for sure I saw that, but that's what I remember, I</p> <p>8 can tell you. But if you can put up a document to</p> <p>9 show me, I'll confirm that. But my -- my --</p> <p>10 Q. Sure. Let's go to the deviation</p> <p>11 investigation report, page 7. Same exhibit,</p> <p>12 Number 5.</p> <p>13 A. Thank you.</p> <p>14 Q. That's the report I'm using. Page 7</p> <p>15 of 236. Very bottom of the page.</p> <p>16 A. So you said the very bottom of the</p> <p>17 page 11 --</p> <p>18 Q. Page 7 of 236.</p> <p>19 A. I'm sorry.</p> <p>20 Q. The bottom of the page.</p> <p>21 A. 7.</p> <p>22 Q. And you see it says that:</p> <p>23 "Based on the investigation and</p> <p>24 evaluation of the current Valsartan route of</p>	<p style="text-align: right;">Page 196</p> <p>1 just -- they just threw out some hypothesis there.</p> <p>2 Q. Okay. It then says:</p> <p>3 "Furthermore, during the tetrazole</p> <p>4 formation step, dimethylformamide may be</p> <p>5 susceptible to low level decomposition under high</p> <p>6 temperature to produce trace amount of</p> <p>7 dimethylamine either via thermo decomposition or</p> <p>8 hydrolysis."</p> <p>9 Do you see that?</p> <p>10 A. I saw that, too.</p> <p>11 Q. And do you agree with me that the</p> <p>12 DMF that was introduced to the zinc chloride</p> <p>13 process may have contained trace amounts of</p> <p>14 dimethylamine as an impurity at the time that it</p> <p>15 was being used for the manufacturing? Do you</p> <p>16 agree with that?</p> <p>17 A. You said may contain that, right?</p> <p>18 Q. Yes. Do you agree with that?</p> <p>19 A. Yes, it is possible.</p> <p>20 Q. And do you also agree that during</p> <p>21 the tetrazole formation step, the DMF may have</p> <p>22 decomposed under the temperatures that were</p> <p>23 applied to it to produce trace amounts of</p> <p>24 dimethylamine either via thermal decomposition or</p>
<p style="text-align: right;">Page 195</p> <p>1 synthesis (zinc chloride process), this</p> <p>2 impurity -- which they're referring to NDMA -- is</p> <p>3 most likely formed during the 'azide quenching' by</p> <p>4 nitrous acid of the API manufacturing process."</p> <p>5 Do you see that?</p> <p>6 A. Yes, I do see that.</p> <p>7 Q. "Specifically, DMF, one of the</p> <p>8 solvents used in Step 4 (Crude) stage, may contain</p> <p>9 trace amount of dimethylamine as an impurity."</p> <p>10 Do you see that?</p> <p>11 A. I saw that, too.</p> <p>12 Q. Do you know when ZHP first learned</p> <p>13 that DMF can contain dimethylamine as an impurity?</p> <p>14 A. I don't know when they first learned</p> <p>15 that, but based on what you read just now, I'm</p> <p>16 reading this paragraph, too. They are saying --</p> <p>17 Q. I just asked if you know when they</p> <p>18 learned that. It's the only question I asked you.</p> <p>19 A. I don't know when they learned that</p> <p>20 specifically.</p> <p>21 But I just want to point out they</p> <p>22 say "may contain trace amounts." So they are</p> <p>23 actually -- I don't think this paragraph is</p> <p>24 showing they know for sure what happened. They</p>	<p style="text-align: right;">Page 197</p> <p>1 hydrolysis?</p> <p>2 Do you agree that's a true</p> <p>3 statement, also?</p> <p>4 A. Again, they are -- they are</p> <p>5 hypothesizing here, right? They are trying to --</p> <p>6 Q. Do you agree with the statement or</p> <p>7 not?</p> <p>8 A. I agree with what they said. That's</p> <p>9 the two possibilities what can actually cause the</p> <p>10 formation of dimethylamine.</p> <p>11 I don't see any direct evidence to</p> <p>12 show to support these are the case, though, or</p> <p>13 either one or both are the case. Or maybe not</p> <p>14 these two, but a third one. So because they point</p> <p>15 out these are two may -- maybe, right? So that</p> <p>16 means there are possibly other ones as well.</p> <p>17 Q. If you look at the bottom of</p> <p>18 page 8 -- go to the bottom of page 8 -- it says:</p> <p>19 "Based on the above elucidated root</p> <p>20 cause, the presence of trace amount of NDMA in the</p> <p>21 final Valsartan API requires the convergence of</p> <p>22 the following three factors (hence the "Three</p> <p>23 Factors Analysis')."</p> <p>24 Did you see what I just read?</p>

<p style="text-align: right;">Page 198</p> <p>1 A. Yes, as you read, that's the last 2 paragraph on page 8. 3 Q. Right. 4 Before right now, were you aware of 5 the Three Factors Analysis that was applied by ZHP 6 in its root cause investigation? 7 A. Yes. 8 Q. Did you talk about the Three Factors 9 Analysis in your report? 10 I don't remember seeing it. Did 11 you? 12 It's just a yes-or-no question, 13 Doctor? 14 A. I didn't mention that in my e-mail 15 -- in my report because again -- 16 Q. That's all I asked. I didn't ask 17 you why. I just asked if it's there or not. 18 A. No, it's not there. 19 Q. Let's go to the top of page 9 where 20 the three factors are listed. 21 Number 1. "Presence of 22 dimethylamine in the manufacturing process, such 23 as its presence in tetrazole formation step." 24 Do you see that?</p>	<p style="text-align: right;">Page 200</p> <p>1 day one because they knew that they were going to 2 put in sodium nitrite and hydrochloric acid and 3 that was going to form nitrous acid, right? 4 A. Yes, I believe so. 5 Q. Number 3. "The possibility of 6 direct contact between secondary amines and 7 nitrite in the presence of the target product." 8 That's number 3, right? 9 A. That's by reading, that's number 3. 10 Q. And in the zinc chloride process, we 11 know the NDMA formed when the dimethylamine was 12 contacted by the nitrous acid, right? 13 A. Well, technically, it's not nitric 14 acid. It's the nitrosonium ion that's formed 15 through multiple steps from nitric acid. 16 Q. The presence of the nitrous acid was 17 necessary to form the NDMA, correct? 18 A. For -- for this particular reaction 19 talk about here, it is correct. 20 But I want to say that nitric acid 21 is not the only reagent that can actually generate 22 nitrosative agent. 23 Q. There's many potential nitrosative 24 agents in the world, but the one that was in this</p>
<p style="text-align: right;">Page 199</p> <p>1 A. I see that sentence. 2 Q. And you agree that the key is that 3 the diethylamine is present. It doesn't matter 4 how it gets there, whether it was an impurity of 5 the DMF to begin with or whether it was a 6 degradation product from the process. 7 It doesn't matter how it gets there. 8 It just matters that it can be there, right? 9 A. For the formation of the NDMA, 10 dimethylamine, as far as we now know as 11 scientists, it's required for the reaction since 12 we know dimethyl -- NDMA is formed during this 13 process. So it's going to be somewhere on the 14 process they have it. 15 Q. It doesn't matter how it got there. 16 It just matters that it was there, right? 17 A. Yes. 18 Q. Number 2. "Presence of nitrous acid 19 in the manufacturing process, such as quenching of 20 azide using sodium nitrite." 21 That's number 2, right? 22 A. That is number 2 by reading. 23 Q. The presence of nitrous acid in this 24 process was well known to the people at ZHP from</p>	<p style="text-align: right;">Page 201</p> <p>1 process was nitrous acid, right? 2 A. No, it's nitrosonium ion. It's not 3 a reagent that's directly from nitric acid. You 4 have -- we have to be clear about that. Because 5 nitric acid is not a nitrosative reagent. It's 6 nitrosonium ion. 7 Q. The nitrosonium ion, you call that 8 as NO plus in your report, right? 9 A. I draw it that way, yes. 10 Q. Could there have been NO+ without 11 the sodium nitrite? 12 A. For this particular reaction, no. 13 Q. So the introduction of the sodium 14 nitrite led to the creation of nitrous acid, and 15 then the nitrosonium ion NO+ was created at some 16 point and that combined with the DMA to create 17 NDMA. 18 Is that your opinion? 19 A. That's the scheme I draw in the -- 20 in my report. 21 Q. And let's go now to page 61 of this, 22 61 of 236. 23 Looking at the bottom part of the 24 page.</p>

<p style="text-align: right;">Page 202</p> <p>1 A. I'm -- can you give me a second? I 2 just get to that page. Thank you. 3 Yes, I'm -- I'm with you now. 4 Q. This is part of the root cause 5 analysis for the TEA process with sodium nitrite 6 quenching. 7 Do you see that? 8 A. So we talk about that. 9 Q. Left column it says "TEA process 10 (with sodium nitrite quenching)"? 11 A. I'm sorry. So you talk about the 12 right column? 13 Q. Left column. 14 A. Oh, hold on. I lost it. 15 Q. It says "TEA process (with sodium 16 nitrite quenching)." 17 A. Oh, yeah. So the last column said 18 that, yes. 19 Q. And if you go to the right, it says: 20 Number 1. "Triethylamine 21 hydrochloride was used as catalyst. Sodium 22 nitrite was used for quenching after reaction." 23 You see that? 24 A. Yes, I do see that.</p>	<p style="text-align: right;">Page 204</p> <p>1 to read each sentence, right? So just now by 2 reading number 2, I had a puzzle. 3 Q. Have you ever seen this page before? 4 Do you know? 5 A. I cannot -- I cannot remember from 6 off my mind -- head, no. 7 Q. Looking now at page 61 of 236 of 8 this deviation investigation report where they're 9 talking about the TEA process with sodium nitrite 10 quenching, on the right-hand side it says: 11 "Number 3. "Triethylamine 12 hydrochloride may contain diethylamine and 13 dimethylamine, react with nitrous acid (formed by 14 sodium nitrite and hydrochloric acid) during the 15 next quenching reaction, and NDMA and NDEA may be 16 formed." 17 Is that an accurate statement as a 18 matter of chemistry? 19 A. Well -- 20 Q. Do you disagree with ZHP's analysis? 21 A. In term of chemistry, at the same of 22 what they say, if the TEA hydrochloride contain, 23 right? So there's an assumption. If this 24 catalyst used in this particular process, this</p>
<p style="text-align: right;">Page 203</p> <p>1 Q. It says: 2 Number 2. "No DMF solvent is added 3 in crude step, and no dimethylamine will be 4 degraded." 5 See that? Do you see what I just 6 read, number 2? 7 A. So number 2 is reading "No DMF 8 solvent is added in crude step, and no 9 dimethylamine was -- will be degraded." 10 Q. That's what I just read, correct? 11 A. By reading, that's correct, but that 12 doesn't make much sense to me, though. 13 Q. Have you ever seen what I'm showing 14 you right now? Have you ever seen this before? 15 A. Well, I see -- I read many things. 16 Q. Doctor, I understand you read a lot 17 of things. I'm asking if you read this. 18 MR. BERNARDO: He's trying to 19 answer your question. Please stop 20 interrupting him. 21 THE WITNESS: Yeah. 22 BY MR. SLATER: 23 Q. Okay. 24 A. I possibly did, but I just -- I need</p>	<p style="text-align: right;">Page 205</p> <p>1 particular step contain diethylamine and 2 dimethylamine, that's the assumption. If they 3 contain those, they can actually react with 4 nitrous -- nitrous acid, which is formed through 5 the sodium nitrite with hydrochloric acid. That's 6 correct. 7 Q. Let's go to 52 of 236, please. 8 Looking at the top of the page, this 9 says in part: 10 "Based on the investigation and the 11 evaluation of the route of synthesis, NDEA is most 12 likely formed in Step 4 crude stage, where toluene 13 is used as solvent and triethylamine hydrochloric 14 as catalyst for the tetrazole formation." 15 Do you see what I just read? 16 A. I think you read it right. 17 Q. Do you agree with that statement 18 that that's the most likely point in the process 19 when the NDEA was formed? 20 A. Based on the scheme that the -- 21 these people using, based on my knowledge of 22 chemistry, that is the step where NDEA was formed. 23 Q. It then says -- rephrase. 24 This report states:</p>

<p style="text-align: right;">Page 206</p> <p>1 "Specifically, triethylamine (TEA) 2 may contain trace amount of diethylamine as an 3 impurity." 4 Are you aware of that, that an 5 impurity of triethylamine can be diethylamine? 6 A. Well, I didn't -- I think you didn't 7 read it, the whole sentence. What I'm reading is 8 "Furthermore, triethylamine may be susceptible to 9 low level decomposition" -- 10 Q. I didn't -- I didn't read that 11 sentence because that's not what I asked you 12 about. It's a separate sentence. 13 I don't understand, Doctor. Can you 14 just stick with what my question, please? 15 A. Right. But I need to first 16 understand which sentence you are reading because 17 you are -- 18 Q. You didn't understand which sentence 19 I read? I read the sentence. I'll do it again. 20 I'm sorry. Let's -- let's try this again. 21 It states: 22 "Specifically, triethylamine (TEA) 23 may contain trace amount of diethylamine as an 24 impurity."</p>	<p style="text-align: right;">Page 208</p> <p>1 hypothetical, right? So I read those. Honestly, 2 that doesn't mean too much to me because they may 3 contain also means may not contain. 4 Q. What's your opinion? 5 Does -- does triethylamine 6 potentially contain trace amounts of diethylamine 7 as an impurity when it's purchased? 8 A. My con -- my opinion -- 9 Q. Do you have an opinion one way or 10 another on that question? 11 A. I don't know what ZHP bought, right? 12 I cannot judge whether any impurity, including 13 diethylamine was part of the TEA they bought, 14 right? But what I can say my opinion is, this 15 sentence really doesn't show anything really 16 specific. It says "may contain trace amount of 17 diethylamine." It also mean may not contain. 18 So I -- 19 Q. That's your reading of this? Okay. 20 That's fine. 21 A. Yeah. 22 Q. Now, I'm going to ask you again just 23 so we're clear. We move on. 24 Do you have an opinion as to whether</p>
<p style="text-align: right;">Page 207</p> <p>1 I want to ask you. 2 Are you aware that triethylamine may 3 contain a trace amount of diethylamine as an 4 impurity? Are you aware of that? 5 A. So where this -- 6 Q. Yes or no. 7 A. Where this sentence is? 8 Q. It's right in front of your face. I 9 just read it to you. Three lines down, it says: 10 "Specifically, triethylamine may 11 contain trace amount of diethylamine as an 12 impurity." 13 Do you see that? 14 A. In the first paragraph? 15 Q. Yes. 16 A. "Specifically, triethylamine may 17 contain trace amount of diethylamine as an 18 impurity." 19 Yes, I read that. Correct. 20 Q. Did you know that before I just read 21 it to you that diethylamine can be an impurity of 22 triethylamine? 23 A. Well, my read is triethylamine may 24 contain trace amount. So these statement are all</p>	<p style="text-align: right;">Page 209</p> <p>1 or not the triethylamine that was used by ZHP 2 potentially contained trace amounts of 3 diethylamine as an impurity? Yes or no. Do you 4 have an opinion on that or not? 5 A. I don't have opinion on that. 6 Q. This states: 7 "Furthermore, triethylamine may be 8 susceptible to low level decomposition under 9 certain conditions to produce trace amount of 10 diethylamine." 11 Do you see the sentence I just read? 12 A. I did. 13 Q. Do you have an opinion as to whether 14 or not the triethylamine was susceptible to low 15 level decomposition under certain conditions to 16 produce trace amount of diethylamine? 17 A. This sentence, again, is very vague. 18 That's like all hypothetic. "May be susceptible 19 to low level." All these words are doesn't really 20 show anything scientifically. 21 So I think I just say I don't have 22 any opinion on this. Because this is really 23 doesn't show anything that is scientific, right? 24 So it may make susceptible means possibility,</p>

<p style="text-align: right;">Page 210</p> <p>1 right? So -- or there is a chance, right? So I</p> <p>2 don't see why this provide anything that's</p> <p>3 specific.</p> <p>4 Sorry.</p> <p>5 Q. Do you see at the bottom of the</p> <p>6 page. Let's scroll down just a tiny bit.</p> <p>7 "Conditions for NDEA formation."</p> <p>8 And you see it says:</p> <p>9 "The presence of trace amount of</p> <p>10 NDEA in the final Valsartan drug substance</p> <p>11 requires the convergence of the following three</p> <p>12 factors."</p> <p>13 Do you see that?</p> <p>14 A. You talk about the next bullet,</p> <p>15 right? Number 3. "Conditions for NDEA</p> <p>16 formation," right?</p> <p>17 Q. Correct.</p> <p>18 A. There's a bunch of Chinese and then</p> <p>19 you read the first. You read the sentence in</p> <p>20 between that "The presence of trace amount of NDEA</p> <p>21 in the final Valsartan drug substance requires the</p> <p>22 convergence of the following three factors."</p> <p>23 Yes, I saw that.</p> <p>24 Q. And the three factors:</p>	<p style="text-align: right;">Page 212</p> <p>1 between secondary amines and nitrite in the</p> <p>2 presence of the target product."</p> <p>3 That's the third factor listed,</p> <p>4 right?</p> <p>5 A. If you need to form the NDEA, this</p> <p>6 is what you have to make the two things together.</p> <p>7 That -- that just said nothing, but based on the</p> <p>8 analysis from ZHP, what the potential. They</p> <p>9 actually did the backward analysis.</p> <p>10 If we know now this impurity is</p> <p>11 formed, what are the required reagent. There are</p> <p>12 two of them required to form this product, and</p> <p>13 these two required species must be together.</p> <p>14 So that's -- that's what they</p> <p>15 actually do here.</p> <p>16 Q. When they refer to "in the presence</p> <p>17 of the target product," they're talking about the</p> <p>18 fact that when the quenching takes place, the</p> <p>19 target product is still present in the mixture,</p> <p>20 right?</p> <p>21 A. Can I read that sentence one more</p> <p>22 time? So to understand what the target product</p> <p>23 is?</p> <p>24 "The possibility of direct" --</p>
<p style="text-align: right;">Page 211</p> <p>1 Number 1. "Presence of diethylamine</p> <p>2 in the manufacturing process; such as its presence</p> <p>3 in quenching step."</p> <p>4 Do you see that?</p> <p>5 A. I do.</p> <p>6 Q. It doesn't matter how the</p> <p>7 diethylamine got there. It just matters that it's</p> <p>8 there, correct?</p> <p>9 A. Well, as we just talk about</p> <p>10 dimethylamine, right? So based off the knowledge</p> <p>11 we learn so far and because right now we know NDEA</p> <p>12 already form, this is a required reagent to get</p> <p>13 NDEA formation.</p> <p>14 Q. Second. "Presence of nitrous acid</p> <p>15 in the manufacturing process, such as quenching of</p> <p>16 azide using sodium nitrite."</p> <p>17 So that's what they state is the</p> <p>18 second factor, correct?</p> <p>19 A. Right. To -- the same reason. To</p> <p>20 make the NDEA as a product, you need two</p> <p>21 reactions. So the second it talk about the</p> <p>22 formation of the second reaction.</p> <p>23 Q. Third it says:</p> <p>24 "The possibility of direct contact</p>	<p style="text-align: right;">Page 213</p> <p>1 (reads document).</p> <p>2 Yes. My -- my understanding is the</p> <p>3 target product talk about the drug molecule.</p> <p>4 Q. If ZHP had chosen to extract the</p> <p>5 target product, the crude valsartan from the</p> <p>6 mixture before quenching, then the product would</p> <p>7 not have been contaminated with the nitrosamines</p> <p>8 in either process, right?</p> <p>9 A. So if I understand what you describe</p> <p>10 is, you are saying if -- if ZHP decide to do the</p> <p>11 extraction before you add the nitrite, right?</p> <p>12 That's what you described?</p> <p>13 Q. Correct.</p> <p>14 A. If that's the case, no, you won't be</p> <p>15 able to form. Based on this hypothesis, right?</p> <p>16 These two other reactions. You need to see each</p> <p>17 other. If you don't let them see other, you</p> <p>18 don't -- before you actually purify a compound,</p> <p>19 then you don't have a chance to form the product.</p> <p>20 That's correct.</p> <p>21 Q. Do you agree --</p> <p>22 MR. SLATER: You can take that</p> <p>23 down, Chris, for now. Thanks.</p> <p>24 BY MR. SLATER:</p>

<p style="text-align: right;">Page 214</p> <p>1 Q. Do you agree with me -- well, let me 2 ask it differently. 3 Do you have any understanding as to 4 whether or not ZHP was required to make every 5 feasible technical effort to prevent the formation 6 of genotoxic or carcinogenic compounds during the 7 drug substance synthesis and drug product 8 manufacturing for valsartan? 9 MR. BERNARDO: Object to the 10 form of the question. Vague. Compound. 11 Argumentative. 12 Go ahead, Dr. Xue. 13 THE WITNESS: Can you make 14 the question shorter? Because you have a 15 long question here. 16 BY MR. SLATER: 17 Q. Was ZHP required to make every 18 feasible technical effort to prevent the formation 19 of genotoxic or carcinogenic compounds during the 20 manufacture of valsartan? 21 MR. BERNARDO: Object to the 22 form of the question. Also, beyond the 23 scope of his report and area of 24 expertise.</p>	<p style="text-align: right;">Page 216</p> <p>1 Q. NDMA and NDEA. Those are genotoxic 2 compounds, right? 3 A. Yes, NDMA and NDEA they are. 4 Q. So if ZHP was required to make every 5 feasible technical effort to prevent the formation 6 of genotoxic or carcinogenic compounds such as 7 NDMA or NDEA, one of the things that they could 8 have done was to do scientific research, correct? 9 MR. BERNARDO: Object to the 10 form of the question. 11 BY MR. SLATER: 12 Q. I'm just asking. Could they -- 13 could they have done scientific research into that 14 subject? 15 A. I think the question is, it's very 16 vague because, as I mention just now, the 17 genotoxic or carcinogenic compound is very broad 18 concept. They are also related to the disease and 19 also dose and time. All these things. So it's 20 hard to -- for ZHP to decide what is the scope 21 they have to control. 22 Although I'm not a regulatory 23 scientist, I'm trying to answer here. 24 Yes, I put myself at the situation</p>
<p style="text-align: right;">Page 215</p> <p>1 THE WITNESS: I really hope I 2 can, but I honestly I'm not a regulatory 3 scientist. The requirement from FDA or 4 genotoxicity requirement, all these 5 things I'm not familiar with. 6 BY MR. SLATER: 7 Q. From the perspective of organic 8 chemistry, if an organic chemist who was involved 9 with these processes at ZHP was required to make 10 every feasible technical effort to prevent the 11 formation of genotoxic or carcinogenic compounds 12 as part of these processes, you would agree it 13 would have been feasible for them to do scientific 14 research, right? 15 MR. BERNARDO: Object to the 16 form of the question. Vague. Calls for 17 speculation. 18 THE WITNESS: So I'm not 19 quite clear what compound you talk about. 20 Because genotoxic compound I don't know. 21 I don't have a full list. I assume 22 there's hundreds, if not thousands, of 23 them. 24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 217</p> <p>1 to do research or to develop a drug. If you ask 2 me what I need to -- I absolutely need to, I want 3 to do everything that I can to control everything 4 to the best of what I can. 5 But what is the scope that I need to 6 be aware of, right? So that's the question. If I 7 don't know in my process of NDEA, NDMA, or any 8 other nitrosamine or any compound, right? That 9 is -- that is on the -- on the warning table or on 10 the genotoxic or carcinogenic list, I don't think 11 it's reasonable for -- for anybody to be required 12 to just go out to test everything on the list. 13 I don't -- I'm not, again, develop a 14 drug past FDA yet, but I know in my lab, we -- we 15 pretty much try to learn based on the knowledge or 16 science available to us and develop our risk 17 assessment. 18 If something happened, we go back 19 and do those root cause unless trying to fix 20 the -- the reaction so we don't -- we don't -- we 21 don't have this issue anymore. So that's the 22 practice. 23 I really don't think it's -- it's -- 24 it's reasonable to require a company when they --</p>

<p style="text-align: right;">Page 218</p> <p>1 they really don't -- they don't know what -- what</p> <p>2 is -- like you said, what -- what is the scope.</p> <p>3 What -- what -- what are the things on the radar</p> <p>4 they have to pay attention. If you don't know,</p> <p>5 how can I design something to avoid that?</p> <p>6 Q. One of the things they knew was what</p> <p>7 chemicals and solvents they were introducing into</p> <p>8 the process, right?</p> <p>9 A. I --</p> <p>10 Q. It's a yes-or-no question.</p> <p>11 Did they know what --</p> <p>12 A. For that I agree. They know what</p> <p>13 they use and they know --</p> <p>14 Q. Doctor, I asked a very simple</p> <p>15 question.</p> <p>16 Did the people at ZHP know what</p> <p>17 chemicals and substances they introduced into the</p> <p>18 manufacturing processes?</p> <p>19 A. They do know and I think --</p> <p>20 Q. So the answer is, yes, they knew?</p> <p>21 MR. BERNARDO: Let -- let him</p> <p>22 finish his answer.</p> <p>23 MR. SLATER: Well, maybe you</p> <p>24 could ask your expert when I ask him such</p>	<p style="text-align: right;">Page 220</p> <p>1 So you just ask me whether ZHP</p> <p>2 know what they use in there. My answer</p> <p>3 is, yes. But -- but whether they will</p> <p>4 know what's -- what's going to be</p> <p>5 available next decade about this</p> <p>6 compound, I will say, no, they probably</p> <p>7 don't know at this moment.</p> <p>8 BY MR. SLATER:</p> <p>9 Q. Simple question.</p> <p>10 Did ZHP know what chemicals and</p> <p>11 substances were used in its manufacturing</p> <p>12 processes for valsartan? Yes or no.</p> <p>13 A. They know.</p> <p>14 MR. BERNARDO: Object to the</p> <p>15 question.</p> <p>16 THE WITNESS: I'm sorry.</p> <p>17 MR. BERNARDO: Object to the</p> <p>18 form of the question asked and go on.</p> <p>19 THE WITNESS: My answer is,</p> <p>20 yes, they know based on the time and the</p> <p>21 knowledge around them.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Were the chemists and the people at</p> <p>24 ZHP responsible to know that certain structural</p>
<p style="text-align: right;">Page 219</p> <p>1 a simple question, just answer it and not</p> <p>2 go on to a speech.</p> <p>3 MR. BERNARDO: He's qualifying</p> <p>4 his answer, which he's permitted to do,</p> <p>5 and you're jumping on top of his</p> <p>6 question. Let him just finish.</p> <p>7 THE WITNESS: Well, I -- yeah,</p> <p>8 I'm sorry if I went long.</p> <p>9 But you asked me whether ZHP</p> <p>10 knows what they put in their reaction</p> <p>11 vessel, my answer is, yes, they know.</p> <p>12 But you will ask me whether</p> <p>13 they should know every single thing about</p> <p>14 every single reaction of everything they</p> <p>15 add into their reaction vessel, that kind</p> <p>16 of requirement with my training as a</p> <p>17 scientist, I think that's a little too</p> <p>18 much.</p> <p>19 Because science is growing,</p> <p>20 right? Evolving, right? So we know</p> <p>21 certain compound have this character.</p> <p>22 That's our current knowledge. Next year</p> <p>23 or next decade that knowledge might</p> <p>24 expand, right?</p>	<p style="text-align: right;">Page 221</p> <p>1 groups, including N-nitroso-compounds such as NDMA</p> <p>2 and NDEA, were considered to have extremely high</p> <p>3 carcinogenic potency and that they were excluded</p> <p>4 from the threshold approach --</p> <p>5 MR. BERNARDO: Objection.</p> <p>6 BY MR. SLATER:</p> <p>7 Q. -- about evaluation of impurities in</p> <p>8 drug substances?</p> <p>9 MR. BERNARDO: Object to the</p> <p>10 form of the question. Assumes facts.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Do you know whether they were</p> <p>13 supposed to know that or not?</p> <p>14 MR. BERNARDO: Object to the</p> <p>15 form of the question. Assumes facts.</p> <p>16 Compound. Vague.</p> <p>17 Go on, Dr. Xue.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. It's a yes or no. Do you know</p> <p>20 whether they were supposed to know that or not?</p> <p>21 A. Well, in your question, you describe</p> <p>22 NDMA and NDEA as extremely toxic compound. For</p> <p>23 that I disagree because they are DNA modifiers.</p> <p>24 There are publications document about these</p>

<p style="text-align: right;">Page 222</p> <p>1 compounds to show they are potential or 2 probable -- probable cancer-causing -- causing 3 reagent, right? 4 So even FDA, they are not super 5 clear whether these are direct -- there is direct 6 evidence to show these particular compounds are 7 actually the direct cause of cancers. 8 So I don't think it's right at this 9 moment we characterize them as extremely toxic 10 cancer-causing compounds. 11 MR. SLATER: Let's go to the 12 FDA Guidance for Industry from December 13 2008. I guess that will be Exhibit 9. 14 MR. BERNARDO: And, Adam, when 15 you're at a point to break, we've been 16 going about an hour and 10 minutes and 17 I'd appreciate. 18 MR. SLATER: Well, I'm going 19 to ask a couple more questions about this 20 and then we can break. 21 MR. BERNARDO: All right. 22 (Document marked for 23 identification as Xue Exhibit 9.) 24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 224</p> <p>1 or not ZHP needed to be vigilant to ensure that if 2 there were any such compounds as I just read in 3 that sentence produced as part of their 4 manufacturing process for valsartan that they 5 needed to identify them? 6 A. So that sentence you were just 7 reading, right, if I want to repeat what you just 8 read, there are some compound containing certain 9 chemical structures, structure groups. 10 So nitrosamine, as here it says 11 nitroso compound, that's what we discuss here, 12 right? It's -- it's a group of compound which 13 contains infinitive number of nitroso compound, 14 right? So that's like everything has a nitroso 15 group is called a nitroso compound. 16 Here you talk about there are 17 evidence to show some compound containing this. I 18 really don't think we can actually just say every 19 nitroso compound here. Okay? That -- 20 Q. Do you disagree with the FDA 21 guidance? 22 A. I disagree with what you 23 interpret -- interpret just now. I strongly 24 disagree.</p>
<p style="text-align: right;">Page 223</p> <p>1 Q. This is Exhibit 9. The FDA's 2 Guidance for Industry. "Genotoxic and 3 Carcinogenic Impurities in Drug Substances and 4 Products: Recommended Approaches" December 2008. 5 Have you ever seen this document 6 before? 7 A. I don't remember it particularly. 8 Q. Let's go to page 8. Top paragraph. 9 Blow it up a tiny bit. Okay. Perfect. 10 At the top of page 8, the last 11 sentence of the carryover paragraph says: 12 "However, there are some compounds 13 containing certain structural groups" and then in 14 parentheses "aflatoxin-like-, N-nitroso-, and 15 azoxy-structures) that have extremely high 16 carcinogenic potency and are excluded from the 17 threshold approach." 18 Do you see what I just read? 19 A. I saw what you just read. 20 Q. Did you know that before I just 21 showed that to you? 22 A. I don't remember reading the exact 23 same sentence, but I can see it now. 24 Q. Do you have an opinion as to whether</p>	<p style="text-align: right;">Page 225</p> <p>1 Because, again, as I wrote in my 2 report it's clear as a science -- as a scientist, 3 right? It's very clear to me when you actually 4 generalize any statement like this, you see 5 nitroso compound it's highly, extremely toxic. 6 That fundamentally is just not correct. 7 Because if you know, right, for any 8 nitroso compound to be -- to become a potential 9 DNA alkylator, a DNA modifier, you have to undergo 10 a process which include a type of enzyme called 11 P450, right? 12 That enzyme has to take the 13 substrate into its active site and every enzyme's 14 active site is very unique. It's not like 15 everything you can take get to the active site. 16 So there are very specific nitroso 17 compound that can be actually take into the active 18 site, and that can potentially. Even if you get 19 into the active site, it doesn't mean it can be 20 turned into an alkylating agent. 21 So it's really not fair to say a 22 nitroso compound because it's a nitroso compound 23 so it must be able to be turned into a DNA 24 alkylating agent.</p>

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1 Q. I didn't ask you that. You know,
2 what, Doctor? I didn't ask you that.
3 In fact, you're not a general
4 causation expert in this case, and with all due
5 respect, I don't need to hear from you general
6 causation testimony. That's not what I asked you.
7 Okay? So I'd appreciate not being given a speech
8 about whether you think that these substances are
9 dangerous or not or anything like that.
10 I'm reading from an FDA guidance and
11 asked you a different question which, with all due
12 respect, you didn't answer.
13 So I'm going -- I'm going to try it
14 again.
15 Do you have any opinion as to the
16 level of scientific research and analysis ZHP
17 needed to do to make sure that they identified any
18 N-nitroso-compounds that were created during the
19 manufacture of valsartan?
20 Yes or no. Do you have an opinion
21 as to level of research that they should have
22 done?
23 MR. BERNARDO: Object to the
24 form of the question and the commentary

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1 before, particularly in light of the
2 rephrasing of the question now.
3 MR. SLATER: You know what?
4 I'm going to withdraw the question. I'm
5 going to ask the court reporter to please
6 read back the question I asked before
7 that massive long question -- that long
8 answer that the witness just gave.
9 Because you're right. I
10 didn't rephrase it exactly the same way.
11 So let's go back to the question that
12 wasn't answered the first time.
13 (The reporter read the record
14 on page 224 lines 20-21.)
15 MR. SLATER: No, it was before
16 that.
17 THE WITNESS: I said I
18 disagree with that because --
19 MR. SLATER: Please, Doctor.
20 We're not asking you to say anything
21 right now.
22 MR. BERNARDO: Please don't
23 raise your voice at the witness.
24 MR. SLATER: I'm sorry, but

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1 you know what? If you were in my shoes,
2 you'd be just as frustrated.
3 MR. BERNARDO: I've been in
4 your shoes many times and I don't raise
5 my voice to the witness.
6 (The reporter read the record
7 on page 223 line 24 through page 224
8 line 5.)
9 MR. BERNARDO: Object to the
10 form of the question on the same ground.
11 Asked and answered, particularly in light
12 of the phraseology of that question and
13 the statements in the document.
14 BY MR. SLATER:
15 Q. It's a yes-or-no question. Do you
16 have an opinion or not?
17 A. I do have opinion. I said --
18 Q. Okay.
19 A. -- the way you --
20 Q. I didn't ask you what the opinion
21 was. I asked if you had an opinion.
22 A. I do.
23 Q. Okay. Do you -- is it your opinion
24 that ZHP had to be vigilant to make sure they

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1 identified any nitrosamines that were formed by
2 the processes, or is it your opinion they did not
3 need to be vigilant to try to identify
4 nitrosamines formed by the processes?
5 A. They do not --
6 MR. BERNARDO: Object to the
7 question.
8 THE WITNESS: -- because they
9 don't -- I'm sorry.
10 MR. BERNARDO: Object to the
11 form of the question. Vague.
12 Go on.
13 THE WITNESS: My opinion is
14 they do not because really they have no
15 reason to do any study.
16 This statement, as I
17 mentioned, you use this statement from
18 FDA, but you interpret this statement
19 totally wrong.
20 BY MR. SLATER:
21 Q. There was literature available --
22 and you said it in your report -- it was
23 documented that sodium nitrite applied to a
24 secondary amine could create NDMA or NDEA,

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1 correct? That was literature that was available
2 to ZHP, right?

3 A. My opinion for that is, it's for the
4 secondary amine to react with nitrosonium ion,
5 It's a documented reaction that is not common as
6 the expert of the plaintiffs claim every average
7 chemist should actually know that.

8 Q. It was a documented reaction such
9 that if the chemists at ZHP had done scientific
10 research, they would have been able to find that
11 reaction documented in the literature, correct?

12 A. I disagree.

13 Q. You're saying it's impossible for
14 them to find that in the literature that you told
15 me it's documented in?

16 MR. BERNARDO: Object to the
17 form of the question. The
18 characterization of his answer, and the
19 not allowing him to finish his answer.

20 THE WITNESS: I said that my
21 opinion for this on this topic is very
22 clear.

23 Yes, the reaction for
24 secondary amine to react with nitrosonium

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1 ion to form NDMA is documented, but it's
2 not as common as the expert on the
3 plaintiff side claim.

4 And for why I said it's rare,
5 because the reaction require a reagent
6 that's dimethylamine, which is not -- ZHP
7 didn't aware at all their process can
8 actually produce.

9 So we thought that reactant
10 you cannot possibly expect or foresee the
11 formation of NDMA.

12 Also, I am here as a
13 scientist. I did research on nitrous
14 oxide. I know nitrosonium ion can
15 actually be reactive. So I'm -- I'm not
16 average here anymore. So I know the
17 other part of the reactivity, right?

18 Even me, I don't know the
19 presence of dimethylamine. So I really
20 feel these two together that just, as I
21 concluded or I offer my opinion.

22 I never said there's no way
23 they can figure out this reaction is
24 documented, but the fact that they don't

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1 have a secondary amine in their reaction
2 as designed, and they don't have enough
3 resource to actually figure that out.

4 So it's not fair to expect ZHP
5 to kind of foresee this reaction happened
6 to form NDMA.

7 BY MR. SLATER:

8 Q. You're not saying it could not have
9 been figured out. You're just saying it would
10 have been hard to figure it out.

11 Is that what I understand you're
12 saying?

13 A. What I'm saying is, NDMA formation
14 from dimethylamine and nitrosonium ion is
15 documented but is not common as the expert of the
16 plaintiffs claimed. However, to make it extremely
17 hard is, the two reaction -- one of the two
18 reactant was not there, and ZHP didn't know and
19 not possibly reasonably be expect to know that
20 this dimethylamine can actually -- actually
21 present in their reaction vessel.

22 That's all what I actually offered
23 as my opinion.

24 Q. Are you saying it was impossible for

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1 ZHP to know that DMA was known as one of the
2 primary impurities of DMF?

3 MR. BERNARDO: Object.

4 BY MR. SLATER:

5 Q. Yes or no. Are you saying it was
6 impossible for them to know that?

7 MR. BERNARDO: Object to the
8 form of the question. Vague.

9 THE WITNESS: As a -- as a
10 scientist, right? So I never say
11 anything that is impossible. I like to
12 see experiment. I like to see data.
13 Everything is supported by data by the
14 science. If there is, you know, there's
15 always be ways.

16 I don't want to be exclusive
17 like must be, like some of the
18 plaintiffs' experts was claiming
19 everybody should know this. When you see
20 sodium nitrite, you must be doing this.

21 I just not trained to do that.

22 BY MR. SLATER:

23 Q. You're not trained to do that you
24 said? I didn't hear that.

<p style="text-align: right;">Page 234</p> <p>1 A. Yeah, I just not trained to be</p> <p>2 generalize everything will be absolute on</p> <p>3 anything.</p> <p>4 Q. In terms of what the chemists at</p> <p>5 ZHP -- well, let me ask you this.</p> <p>6 Do you have -- you have no</p> <p>7 understanding of what -- well, rephrase.</p> <p>8 You don't know what the ZHP chemists</p> <p>9 would have found if they did scientific research</p> <p>10 into the potential formation of nitrosamine</p> <p>11 impurities -- well, rephrase.</p> <p>12 You don't know what the ZHP chemists</p> <p>13 would have found if they did research the</p> <p>14 potential impurities of DMF, the potential</p> <p>15 degradation products of DMF, and the potential</p> <p>16 impacts of using sodium nitrite in this process,</p> <p>17 you don't know what they would have found because</p> <p>18 they never did the research, right?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question. Compound. Vague.</p> <p>21 Go on.</p> <p>22 THE WITNESS: Yeah, I cannot</p> <p>23 speculate what result if I don't do that.</p> <p>24 I don't even know if I do something today</p>	<p style="text-align: right;">Page 236</p> <p>1 Sorry.</p> <p>2 Q. Have you seen it before?</p> <p>3 A. Yeah, I don't remember exactly, but</p> <p>4 I think so.</p> <p>5 Q. Let's go to page 7 of 23, please.</p> <p>6 The part I want to focus on is the</p> <p>7 paragraph at the top that says "In addition."</p> <p>8 It's the second paragraph.</p> <p>9 Do you see that?</p> <p>10 A. Yes.</p> <p>11 Q. At the top of the page it says:</p> <p>12 "In addition, as reported in</p> <p>13 'Theoretical Investigation of</p> <p>14 N-nitrosodimethylamine Formation from Nitrosation</p> <p>15 of Trimethylamine, Journal of Physical Chemistry</p> <p>16 2010,' TEA could react with nitrous acid directly</p> <p>17 to form NDEA without proceeding via the</p> <p>18 intermediary of DEA. The reaction mechanism is as</p> <p>19 follows."</p> <p>20 Do you see that?</p> <p>21 A. Yes, I do see that statement.</p> <p>22 Q. Were you aware before right now that</p> <p>23 ZHP concluded that the nitrous acid could directly</p> <p>24 nitrosate the trimethylamine to form NDEA?</p>
<p style="text-align: right;">Page 235</p> <p>1 I didn't do yesterday what I would have</p> <p>2 got. So I cannot speculate.</p> <p>3 MR. SLATER: All right. We</p> <p>4 can take a break now, actually.</p> <p>5 MR. BERNARDO: Okay. Thank</p> <p>6 you.</p> <p>7 THE VIDEOGRAPHER: Time right</p> <p>8 now is 2:54 p.m. We're off the record.</p> <p>9 (Recess).</p> <p>10 THE VIDEOGRAPHER: Time right</p> <p>11 now is 3:08 p.m. We're back on the</p> <p>12 record.</p> <p>13 MR. SLATER: Okay. We're</p> <p>14 going to put up the next exhibit. I</p> <p>15 think it's Exhibit 10 we're up to.</p> <p>16 (Document marked for</p> <p>17 identification as Xue Exhibit 10.)</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Looking on the screen, Exhibit 10,</p> <p>20 this is a document titled "Investigation regarding</p> <p>21 unknown impurity (genotoxic impurity) of Valsartan</p> <p>22 API" and it's Version 3 of this report.</p> <p>23 Do you see this document?</p> <p>24 A. Yes, I do.</p>	<p style="text-align: right;">Page 237</p> <p>1 A. I read this page before, but I don't</p> <p>2 think ZHP concluded this. They just cite this</p> <p>3 reference here to see if that's a possible</p> <p>4 mechanism.</p> <p>5 Q. Do you think these deviation</p> <p>6 investigation reports are just a series of</p> <p>7 statements about what might have happened, or do</p> <p>8 you think they're actually conclusions about what</p> <p>9 likely occurred?</p> <p>10 MR. BERNARDO: Object to the</p> <p>11 form of the question. Vague.</p> <p>12 THE WITNESS: They are a</p> <p>13 bunch of conclusions. They all</p> <p>14 conclusions, but scientifically to me</p> <p>15 they are not conclusions. They are</p> <p>16 speculation. So hypothesis.</p> <p>17 I don't think ZHP or anybody</p> <p>18 here experimentally ever validate whether</p> <p>19 this scheme showing on the -- the PDF</p> <p>20 that you showing me is there's any reason</p> <p>21 this happened.</p> <p>22 I don't remember exactly every</p> <p>23 detail about this paper. This paper</p> <p>24 published in 2010 was actually as the</p>

<p style="text-align: right;">Page 238</p> <p>1 title it's "Theoretical Investigation." 2 There is no experimental evidence to 3 provide whatsoever to support this at 4 all. 5 I don't want to look down at 6 any theoretical investigation because my 7 lab myself, we do theoretical 8 investigation for many of my projects. 9 So, but we always couple these theories 10 or we call hypothesis with experimental 11 proof. 12 So this is definitely 13 something you can hypothesize. And by 14 just looking at the drawing here, that 15 make some sense of why they push the 16 arrow here and going there. 17 And then they can actually 18 conclude with a -- with a hypothesis that 19 the reaction without intermediate can 20 actually theoretically go, but that other 21 than a scientific hypothesis, it doesn't 22 say anything about it. 23 BY MR. SLATER: 24 Q. When you pointed out that the title</p>	<p style="text-align: right;">Page 240</p> <p>1 actually happens when you experiment. 2 Is that what you're saying? 3 A. Normally it's not just one 4 experiment because to -- especially to prove a 5 mechanism like these authors trying to do, it's 6 not a trivial thing, right? So I tell you we do 7 these kind of research a lot, right? 8 So it's a -- it's a -- it's a very 9 well-dedicated desire of a whole series of 10 experiments. Because you cannot, unfortunately, 11 as a chemist, to capture any intermediate or 12 transition state or any of these species on the 13 way. You can only isolate the product to how you 14 actually design an experiment that you can use the 15 product you isolated to prove this arrows that you 16 draw would all be correct. 17 That's really a big chunk of science 18 in organic chemistry. So that's what I do, but 19 I'll say we probably don't have time to go through 20 the detail. But this is very, very difficult and 21 high-end things. You do need to have a lot of 22 experiment to prove one hypothesis -- hypothetical 23 mechanism. 24 Q. That's -- what you're talking about</p>
<p style="text-align: right;">Page 239</p> <p>1 is "Theoretical Investigation," that would be, in 2 other words, for someone like me to say this is 3 something that's potential. It's possible, right? 4 A. You can -- you can say that way. I 5 like to say because, again, I publish paper like 6 this, too, but not exact same topic. I publish 7 papers on theoretical calculation quite a lot. 8 Actually, these are usually -- when I publish, I 9 always have some experimental result there. I use 10 my theory to explain what's going on. 11 If I only have a theory, that, 12 unfortunately, to me I might be bias here because 13 I never publish this way. When I only have a 14 theory pictured in any publication say this is 15 what potentially can happen, I as a reader always 16 have a big question mark join after that title. 17 Say, yes, there's theory comes up, but let's wait 18 for years to -- to test this. 19 Q. So there may be a theoretical 20 possibility, a potential for a reaction to occur 21 like this. In order to determine whether or not 22 that is really going to happen, I think what you 23 said is you need to do an experiment. You need to 24 test that -- that potential outcome and see if it</p>	<p style="text-align: right;">Page 241</p> <p>1 would also be the process of risk assessment. If 2 you're doing a risk assessment of a manufacturing 3 process, like ZHP was doing, they if -- they 4 recognize something could potentially occur, they 5 would need to do experiments and multiple tests to 6 find out what's really happening. 7 Is that what you're saying? 8 A. I agree with you and not agree. 9 Because we -- I remember before the break, we kind 10 of discuss about this, right? 11 So as a scientist, you're going to 12 know what is your hypothesis. When I know my 13 hypothesis -- like these people, these authors, 14 like my lab we do, too, right? We have a theory. 15 We set it up and then we design experiment toward 16 that to prove -- or prove is wrong or right. So 17 it doesn't matter. But we desire experiment to 18 prove. 19 But that goal or that hypothesis we 20 call is number one important in your work. If we 21 don't know, like you just described for ZHP, right 22 now we learn NDMA and NDEA are there, right? 23 So, but before we talk about dozen 24 years ago when we don't know. It's really just</p>

<p style="text-align: right;">Page 242</p> <p>1 for me, as a scientist, I just cannot visualize 2 that.</p> <p>3 Q. This article existed in 2010 and was 4 actually written by people in Beijing, China, 5 correct?</p> <p>6 A. I honestly don't remember the 7 authors at all. I don't know. I usually don't 8 read their institutions where they publish, but, 9 yeah.</p> <p>10 Q. You would agree with me that a 11 thorough scientific search of the literature 12 should have turned up this article because they 13 knew at ZHP they were using triethylamine. They 14 knew that they were going to use tertiary amine.</p> <p>15 So there's no reason why they 16 wouldn't have found this article at least, right?</p> <p>17 MR. BERNARDO: Object to the 18 form of the question. Calls for 19 speculation. Vague.</p> <p>20 THE WITNESS: I'm not at ZHP. 21 I really cannot. I hope I can answer, 22 right?</p> <p>23 So if I -- I just be myself, 24 right? I tell you if I'm in their shoes</p>	<p style="text-align: right;">Page 244</p> <p>1 Q. That's the words on the page, right? 2 That's what the words on the page say?</p> <p>3 A. That are the words on the page that 4 you were reading correctly, too. But as I said --</p> <p>5 Q. I only asked you if that's what it 6 says.</p> <p>7 A. Okay. Those are the words by 8 reading from the document to describe the scheme 9 that they draw as a potential of mechanism.</p> <p>10 Q. If ZHP had seen this article back 11 when they were developing the TEA process with 12 sodium nitrite quenching and when they were 13 actually using it, if they wanted to test to see 14 whether or not the process was yielding NDEA, they 15 could have tested and they could have looked for 16 NDEA to see if it was being formed. They could 17 have done that if they had chosen to.</p> <p>18 That was something that was 19 technologically feasible, correct? If they wanted 20 to, they could have done that, right?</p> <p>21 I'm not asking you whether they 22 needed to or not.</p> <p>23 I'm asking you: If they chose to do 24 a test to see if there was NDEA, they could have</p>
<p style="text-align: right;">Page 243</p> <p>1 what I will do, right? So this is what I 2 will do if I do a search.</p> <p>3 I found this paper. In the 4 title, they do theoretical investigation. 5 I will quickly just scan through the 6 article.</p> <p>7 If -- again, this is just me. 8 I'm not saying I'm the best, but if I see 9 there's no proof of this theory, I skip 10 it. That's me.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. We know that when ZHP read the 13 article -- well, rephrase.</p> <p>14 We know that when ZHP described the 15 article in this report, they concluded based on 16 this article that TEA could react with nitrous 17 acid directly to form NDEA without proceeding via 18 the intermediacy of DEA.</p> <p>19 That's what it says in the report in 20 front of us, correct?</p> <p>21 MR. BERNARDO: Object to the 22 form of the question and the 23 characterization.</p> <p>24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 245</p> <p>1 done that and determined whether there was NDEA, 2 right?</p> <p>3 A. Well, I really here I thought -- if 4 this is me, I did a search, very thorough search. 5 I found this paper reading theoretical 6 investigation. I show this proposal scheme, and 7 then there's no evidence.</p> <p>8 Honestly, this is something -- I 9 don't want to look down to anybody's work, but 10 this is just, you know, things you draw can make 11 sense, right? Like in organic chemistry.</p> <p>12 I teach organic chemistry. I teach 13 high-level organic chemistry. Things like this, 14 as I said, I don't want to be, you know, 15 disrespectful for other people's work, but I will 16 say I will just skip. I won't take it too 17 seriously. That's me.</p> <p>18 And I think -- I think what ZHP 19 using, if I read it correctly, is when they found, 20 right? They found, okay, I have this issue now.</p> <p>21 Let's go back to -- to see what are the 22 possibilities. That's what they propose, one of 23 the possibilities.</p> <p>24 Q. If ZHP had wanted to test to see if</p>

<p style="text-align: right;">Page 246</p> <p>1 NDEA was being formed in the TEA with sodium 2 nitrite quenching process, it would have been 3 technologically feasible to do that. 4 The equipment existed to be able to 5 look for NDEA, right? They could have done that 6 if they wanted to, correct? 7 A. If -- yeah, if the hypothesis is up 8 there, I'm looking for NDEA the method. I don't 9 know whether the method is established, but like 10 you said, the technology, the treatment of should 11 be available. 12 Q. For example, LC-MS or GC-MS you can 13 look for NDMA with that and that's the type of 14 technology used to look for NDEA and NDMA, right? 15 MR. BERNARDO: Object to the 16 form of the question. Compound. 17 THE WITNESS: I disagree 18 because -- 19 BY MR. SLATER: 20 Q. Wait. All right. 21 You disagree that you use mass 22 spectrometry to look for NDEA and NDMA? 23 A. Well, I disagree because there are 24 methods available not just, right? So if you say</p>	<p style="text-align: right;">Page 248</p> <p>1 available, right? 2 A. I believe so because I personally 3 used them. 4 Q. Right. 5 And that was the technology that one 6 could use to look for NDMA and NDEA if you -- if 7 you wanted to in a substance. 8 That's the technology -- two 9 technologies that you can use for that purpose, 10 right? 11 A. Yes. If you have the compound, you 12 can always choose the available technologies, 13 GC-MS, LC-MS. As I said, I use LC and GC both. 14 LC is more feasible for my type of research. 15 Yeah. 16 Q. And did you see the documents 17 showing that ZHP actually was using mass 18 spectrometry technology throughout this time? 19 They were using it going back to at 20 least 2009 going through the 2010s up through the 21 time that this was disclosed in 2018. 22 You've seen some of those documents, 23 right? 24 MR. BERNARDO: Object to the</p>
<p style="text-align: right;">Page 247</p> <p>1 if GC-MS is a potential that I will use, I will 2 say, yes, I will definitely consider GC-MS as a 3 potential to do the analysis. I'm not saying 4 GC-MS is not a potential. 5 What I'm saying is, you cannot just 6 say, okay, so automatically when you have this 7 potential issue, if you already identified this is 8 some impurity, what is the best way? So, you 9 know, I cannot say GC-MS is the best way. You 10 have to look around to see what is out there, 11 right? 12 So I'm developing valsartan. What 13 about other companies do also valsartan? Are 14 they -- what they use. So if I don't -- if I 15 don't have any test, right, so I probably look 16 around and see what everybody else does, right? 17 So I will. That's my practice, 18 right? So I don't want to get myself inventing 19 something which is not like everybody else does. 20 Q. Just to be clear -- 21 A. Uh-huh. 22 Q. -- GC-MS and LC-MS technology 23 existed in 2010, 2011, all the way through. That 24 was technologic -- that was technology that was</p>	<p style="text-align: right;">Page 249</p> <p>1 form of the question. 2 THE WITNESS: There -- there 3 is a lot of documents I saw, and I did 4 remember a lot of document with GC or LC. 5 I believe I saw ZHP used mass spec as 6 their detector to do some experiments. 7 BY MR. SLATER: 8 Q. And let's go -- let's go to the next 9 page if we could, page 8 of 23. At the top. 10 Now, continuing with this deviation 11 investigation report, it says: 12 "Based on the above report and 13 research paper, since TEA, hydrochloride, sodium 14 azide and sodium nitrite were also used in 15 Valsartan (TEA process), NDEA in Valsartan (TEA 16 process) could not only be formed by reaction of 17 DEA and nitrous acid, but also by reaction of TEA 18 with nitrous acid directly, the updated 'Three 19 Factor Analysis' for Valsartan (TEA process) is as 20 follows." 21 Did you see what I just read? 22 A. I saw that first paragraph you just 23 read. I think you read it correct, too. 24 Q. And you see they revised their Three</p>

<p style="text-align: right;">Page 250</p> <p>1 Factor Analysis, which we talked about earlier in 2 the deposition. So now number 1 is "Use of TEA 3 hydrochloride in the process." 4 Do you see that? 5 A. I saw that. 6 Q. And then the second and third. 7 Number 2 is "Use of sodium nitrite 8 in the process of quenching." 9 And then the third factor is 10 "Quenching takes place in the presence of target 11 product and DEA/TEA." 12 Do you see that? 13 A. Yes, I do see both of them. 14 Q. So ZHP concluded that the creation 15 of NDEA in the sodium nitrite with -- in the 16 sodium nitrite quenching -- let me rephrase. I 17 got it backwards. 18 So you now see that ZHP concluded 19 that the creation of NDEA with the TEA with sodium 20 nitrite quenching process could occur just through 21 direct nitrosation of the TEA itself, and that's 22 what they documented here in their report. 23 You see that now, correct? 24 It's what I just showed you. That's</p>	<p style="text-align: right;">Page 252</p> <p>1 mechanism TEA could actually form through direct 2 reaction to get you NDEA experimentally showing 3 with a condition that ZHP been using for their TEA 4 process with quenching. 5 So my own opinion for that 6 particular reaction is, before ZHP and Novartis 7 and Solco, they as a team figured this out through 8 a bunch of teamwork, nobody ever know this 9 reaction under the condition that ZHP was 10 performing can actually take place. 11 Q. And as we discussed, if the chemists 12 at ZHP had come across the literature we just 13 talked about and this concept of nitrosating a 14 tertiary amine, the best way that they could have 15 answered the question of whether this could occur 16 in that manufacturing process would have been to 17 test to see if it was happening. 18 That would have been the best way to 19 get the definitive answer, right? 20 A. Well, there are few assumptions we 21 made here. One is ZHP did a search and find that. 22 So if they don't, if they don't realize or 23 hypothesize the potential formation of NDEA, I -- 24 I personally don't see the motivation why they go</p>
<p style="text-align: right;">Page 251</p> <p>1 the words on the page, correct? 2 A. By reading, that's what they were 3 hypothesizing. I won't say this is conclusion, 4 though. 5 Q. You agree it's possible that that 6 happened, right? 7 A. I don't agree. 8 Q. Okay. So you disagree with ZHP on 9 this point? 10 A. No, I not disagree with ZHP. The 11 paper they publish is really against my -- my -- 12 my knowledge. I -- I really cannot take that 13 scheme and then -- ZHP they may -- they may agree, 14 but I don't agree with that science at all. 15 Q. Did you do anything in your analysis 16 as an expert to prove or disprove what ZHP stated 17 on this page that I just read to you? 18 A. I did a search myself from 19 literature to see the reaction between tertiary 20 amines like TEA, for instance, is one simple 21 tertiary amine with nitrosative reagents like 22 nitrosonium ions, for instance. 23 I didn't see any simple -- any 24 single example to show that without a complicated</p>	<p style="text-align: right;">Page 253</p> <p>1 out for a search. Let's put it aside. 2 If they -- for some reason they had 3 the motivation to do the search, when they see a 4 few papers, including this paper, show up if they 5 happen to see that. I doubt whether they will see 6 it, but if they did like they eventually found it, 7 as I said, as me as a chemist, I read the paper. 8 I will not take it, you know, this there's no 9 evidence or experimental evidence at all happen. 10 I won't do anything for them. 11 So those two -- those two levels, I 12 really just don't see ZHP has a reasonable reason 13 to actually test NDEA in there. 14 Q. You referred to what you would do as 15 a chemist. 16 Do you have any understanding of 17 what the chemists who are working on a process 18 that's to manufacture massive quantities of this 19 substance to be sold around the world to be 20 ingested by humans, do you have an understanding 21 of what their obligation was and what level of 22 scientific analysis they were required to do? 23 Just asking the question. Do you know? 24 A. I --</p>

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1 MR. BERNARDO: Object to the
2 question. Asked and answered.
3 Go on.
4 THE WITNESS: Yeah, I
5 definitely aware the difference of myself
6 and the people who involved in master
7 production of APIs.
8 But I will say the principle
9 that we use for research is the same, and
10 I also want to point out that the
11 database that I use for literature search
12 is not just for academic researchers.
13 Where what I found as a
14 reference is actually available to all
15 the industry people, all the academic
16 people, or actually for you, too. If you
17 go there, right? So that's the same.
18 So I'm -- what I found with
19 this topic, TEA process with quenching,
20 is that there's almost nothing reported
21 about this project -- about this topic,
22 right?
23 I mention that in my report,
24 right? So you probably -- I do research

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1 a lot, but you probably don't, right?
2 You go off other business.
3 But a common reaction if I see
4 a really average chemist that know this
5 reaction or of people in the industry who
6 know this reaction well, it's well known
7 like the expert of the plaintiff they
8 claim, usually if you search for those
9 reaction, you got thousands, tens of
10 thousands hits.
11 This particular reaction, TEA
12 react with whatsoever condition to form
13 NDEA. I mean, talk about any, any
14 mechanism, right?
15 So I did this search.
16 Unfortunately, only can -- can you really
17 feel like with two hands I can count how
18 many hits I got throughout the history.
19 That tells me how little it's known.
20 That's why I also said for
21 this reaction, my opinion is, nothing is
22 known and this condition, now we learn
23 through this case it's a new condition
24 that ZHP, Novartis, and the other part of

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1 the company, they together as a team have
2 figured out.
3 BY MR. SLATER:
4 Q. Well, actually, Novartis wasn't
5 evaluating the TEA with sodium nitrite quenching
6 process, were they?
7 A. Well, they are a part of -- what I'm
8 saying is, they throughout back-and-forth
9 communications, all these knowledge were based on
10 that. And then eventually they happen to learn,
11 okay, there is actually NDMA -- sorry -- NDMA or
12 NDEA formation.
13 I apologize. That's my phone.
14 Q. Let's go up to the -- let's take
15 this down and go to the next exhibit, which will
16 be --
17 A. Can I stop to stop that?
18 Q. Yeah, go ahead. We'll put up the
19 next document while you're doing that.
20 (Document marked for
21 identification as Xue Exhibit 11.)
22 BY MR. SLATER:
23 Q. Let's go to the first page first,
24 and this is Exhibit 11.

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1 Okay. We've put up on the screen an
2 article that is titled "Nitrosative Dealkylation
3 of Some Symmetrical Tertiary Amines."
4 Do you see that?
5 A. I'm sorry. I -- it's 11, right?
6 I'm opening now.
7 Yes.
8 Q. And this is an article that was
9 published in 1979. That's what it says up on the
10 left column from when the download was made.
11 Published on January 1, 1979.
12 A. Okay.
13 Q. And you can actually go to the end
14 of the article if you don't believe me, and it
15 says received 13th of June 1978 at the end of the
16 article to show you this is 1979 that it's
17 published. Okay?
18 And if you look at the first
19 paragraph, it talks about the fact that in the
20 very middle of the paragraph or little further
21 down the middle, it says:
22 "More recently attention has been
23 directed to the public health aspects of the
24 nitrosation of tertiary amines and quaternary

<p style="text-align: right;">Page 258</p> <p>1 ammonium compounds."</p> <p>2 Do you see that?</p> <p>3 A. Yeah, you read it right.</p> <p>4 Q. Then the next sentence says:</p> <p>5 "It has been shown that a wide</p> <p>6 variety of tertiary amines can react with nitrite</p> <p>7 in the pH range of 3 to 6.5 and temperature 37 to</p> <p>8 90 degrees to produce nitrosamines in varying</p> <p>9 yields."</p> <p>10 Do you see that?</p> <p>11 A. You read it right, too.</p> <p>12 Q. So you would agree with me that</p> <p>13 we've talked about at least a few articles now.</p> <p>14 There was literature out there available to ZHP</p> <p>15 that they could have found if they had looked</p> <p>16 indicating that there was the potential for this</p> <p>17 reaction and the reactions in the sodium nitrite</p> <p>18 quenching TEA process to create a nitrosamine.</p> <p>19 There was -- that literature was</p> <p>20 available to show them this is something that</p> <p>21 could potentially happen under certain</p> <p>22 circumstances, correct?</p> <p>23 A. By reading that paragraph the author</p> <p>24 wrote, you're reading is definitely correct.</p>	<p style="text-align: right;">Page 260</p> <p>1 '80s, there's a big confusion or</p> <p>2 people -- not confusion.</p> <p>3 When they report, they</p> <p>4 actually put aniline, which is aromatic</p> <p>5 amino group belong to tertiary amines.</p> <p>6 So many of examples in these papers they</p> <p>7 are actually citing actually -- actually</p> <p>8 having is not truly trialkylamines like</p> <p>9 TEAs or DMAs or these -- these amines.</p> <p>10 Instead they actually talk</p> <p>11 about anilines. So anilines and real</p> <p>12 trialkyl tertiary amines are totally</p> <p>13 different family of compound in terms of</p> <p>14 their consistency because they have</p> <p>15 different PKAs.</p> <p>16 And that's why, right, so</p> <p>17 these authors -- that's my second</p> <p>18 point -- point out. So as the peak range</p> <p>19 for this reaction is also very critical.</p> <p>20 They didn't see anything like 1 or 2 or</p> <p>21 even 2 to 3. They specify saying 3 to</p> <p>22 6.5 because that's -- that's -- you see</p> <p>23 it's just a range of pH, but that's</p> <p>24 actually not.</p>
<p style="text-align: right;">Page 259</p> <p>1 Q. And, again, if ZHP had done that</p> <p>2 research, found this literature, if they wanted to</p> <p>3 know if this was a problem or an issue with their</p> <p>4 manufacturing process, they could have run</p> <p>5 straightforward testing to determine whether or</p> <p>6 not NDEA was being created.</p> <p>7 That was something they could have</p> <p>8 done in response to this literature, right?</p> <p>9 MR. BERNARDO: Object to the</p> <p>10 form of the question. Vague.</p> <p>11 THE WITNESS: I think there</p> <p>12 are two things. One is if you by just</p> <p>13 reading what -- what this literature</p> <p>14 said, right?</p> <p>15 So it says "attention has been</p> <p>16 directed to the public health aspects of</p> <p>17 the nitrosation of tertiary amines and</p> <p>18 quaternary ammonium compounds," and</p> <p>19 there's really not much.</p> <p>20 They also have a few citations</p> <p>21 there, but these paper, I cannot say I</p> <p>22 read every single paper of this field.</p> <p>23 That's not fair. I try to.</p> <p>24 So back then in the '70s or</p>	<p style="text-align: right;">Page 261</p> <p>1 If you read this reference</p> <p>2 when they talk about the tertiary amine,</p> <p>3 unfortunately, they are not really</p> <p>4 tertiary amine. They are aniline</p> <p>5 analogs. These compound under this range</p> <p>6 of pH will stay neutral. What I mean --</p> <p>7 I probably go through too much technical.</p> <p>8 You actually have the nitrogen</p> <p>9 stay neutral. You maintain the</p> <p>10 reactivity. That's how you actually.</p> <p>11 All these connected studies in this paper</p> <p>12 listed all make sense because you have</p> <p>13 the activity there.</p> <p>14 However, the real tri --</p> <p>15 tri -- trialkylamines or tertiary amines</p> <p>16 like a TEA or DMA, they are not. Their</p> <p>17 PK is much higher, right?</p> <p>18 Under this particular</p> <p>19 condition, they will not be able to</p> <p>20 react. That's why people also point out</p> <p>21 in papers, publications, say, wait, wait,</p> <p>22 wait.</p> <p>23 If you have these particular</p> <p>24 aniline-like compound they could react</p>

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1 but they have a real trialkylamine or
2 tertiary amine, they won't react. The
3 range of the pH is critical here.
4 So if I see this, I would say
5 ZHP that is using for their printing
6 process, which if I remember correctly is
7 3 or below, right? They -- they use
8 their strong acid to quench it to below
9 3. So that's -- that's the range 3D
10 printer TEA at least on theory.
11 I'm not trying to say that at
12 this -- at today we don't form NDEA.
13 Yes, we do have NDEA formed. I said
14 earlier, right, this is a really great
15 example to show that, okay, the teamwork
16 actually identified this particular
17 condition for the -- for this reaction
18 generate NDEA. That's the result.
19 But, I mean, all these
20 evidence that you show, it doesn't
21 support at all to show that there's a
22 chance for the reaction to take place.
23 BY MR. SLATER:
24 Q. When you're looking at these

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1 articles --
2 A. Uh-huh.
3 Q. Well, rephrase.
4 Do you think that the people at ZHP
5 should have looked at literature like this? If
6 they had actually looked for it and found it and
7 said, well, let's find all the reasons why this
8 article doesn't raise a risk so we don't have to
9 do a test?
10 Or do you think as a matter of risk
11 assessment they should have said, you know what?
12 These are potential reactions in general. Let's
13 be sure that it's not going to happen with this
14 process so that we're positive that this genotoxic
15 impurity is not being formed.
16 Wouldn't the better practice be as
17 risk assessment to be conservative and careful and
18 actually run the test based on literature like
19 this?
20 MR. BERNARDO: Object to the
21 form of the question.
22 THE WITNESS: Risk assessment
23 is definitely something we need to be
24 very careful, right? So everybody do

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1 research be very careful with reactions.
2 But as I said, the back-and-forth, the
3 hypothesis is important. What am I
4 facing if I don't know? Like ZHP, they
5 don't know on their radar NDEA for this
6 case in their TEA process with quenching
7 is a potential.
8 I just don't feel that's
9 reasonable to expect that.
10 BY MR. SLATER:
11 Q. Did you -- I'm sorry. I didn't mean
12 to interrupt you.
13 Do you think that they should have
14 known there was a risk of NDEA before they went
15 and did their literature search? Is that your
16 testimony?
17 A. My opinion was they don't know, and
18 there's no reason for them to know this reaction
19 can take place. So they didn't take any action,
20 right?
21 Q. And they didn't do any research
22 because they didn't know.
23 Is that what you're saying?
24 Your understanding is because -- let

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1 me ask it clean.
2 A. Right.
3 Q. Your understanding is because they
4 didn't know at the starting point that there was a
5 risk of NDEA or NDMA, they didn't need to do -- go
6 do scientific research to determine whether there
7 was a potential issue?
8 MR. BERNARDO: Object to the
9 form of the question.
10 BY MR. SLATER:
11 Q. Is that what you're telling me?
12 MR. BERNARDO: Vague. Asked
13 and answered.
14 THE WITNESS: I really don't
15 know what else I can add, right? So
16 it's --
17 BY MR. SLATER:
18 Q. Well, it's a yes-or-no question.
19 Maybe you can say yes or no as to whether I'm
20 right or not in understanding your opinion.
21 I'm not looking for a speech.
22 I just want to know yes or no; is
23 that correct?
24 A. My opinion is they don't know.

<p style="text-align: right;">Page 266</p> <p>1 That's -- that's clear. I want to make it very 2 clear. They don't know. 3 And second, there's almost no reason 4 or there's no reason for them to -- for us to 5 expect them to know back then, right? 6 So now, of course, in the year 2020 7 or even 2018 you figure out. After you figure 8 out, it's easy to explain. But before you figure 9 out, back then when they actually developed these, 10 I just don't feel it's fair for anybody to be 11 expected to -- to know everything about the 12 future. 13 Q. All right. You understand that 14 these scientists and people at ZHP were not just 15 doing theoretical evaluation of the literature. 16 Well, rephrase. 17 You understand that what we're 18 talking about here is a risk assessment for a 19 manufacturing process for a drug that's going to 20 then go into the human body. 21 You understand we're talking about a 22 risk assessment, right? Just yes or no. Do you 23 understand we're talking about -- 24 A. Yes, I do understand we talk about</p>	<p style="text-align: right;">Page 268</p> <p>1 impurities from the chemicals and substances in 2 that process? 3 I'm not asking if they had to rule 4 out every genotoxic impurity on earth. 5 But did they have to at least assess 6 for the risk of genotoxic impurities from the 7 potential reactions of the chemicals that they 8 were mixing together in that process? 9 Yes or no. Do you have an 10 understanding of whether they were required to do 11 that? 12 MR. BERNARDO: Object to the 13 form of the question. Asked and 14 answered. 15 THE WITNESS: I don't -- 16 BY MR. SLATER: 17 Q. Yes or no. 18 A. I don't think they're required to do 19 that because although you kind of -- 20 Q. That's fine. You said you don't 21 think so. Okay. Got it. 22 Looking at the article. 23 A. Yes. 24 Q. At the top, there's a little summary</p>
<p style="text-align: right;">Page 267</p> <p>1 risk assessment. 2 Q. And you understand, as I showed you 3 before, the risk assessment needed to ensure that 4 there were no unidentified genotoxic impurities. 5 You understand that was one of the things they 6 needed to do. 7 Do you accept that that's part of 8 the purpose of the risk assessment they had to do? 9 Yes or no. 10 MR. BERNARDO: Object to the 11 form of the question. 12 THE WITNESS: I don't 13 think -- I don't agree that they have to 14 assess every single potential genotoxic 15 compound because there's -- I don't -- I 16 don't -- I don't know. Tell me if there 17 are people doing that. 18 BY MR. SLATER: 19 Q. I didn't ask that. That's not what 20 I asked you. So I'll be clearer. 21 The risk assessment for these 22 manufacturing processes that are at issue, do you 23 accept that the risk assessments needed to take 24 into account the potential creation of genotoxic</p>	<p style="text-align: right;">Page 269</p> <p>1 and in the third line it says: 2 "The rate of formation of 3 diethylnitrosamine was found to be first order in 4 nitrous acid, triethylamine, and in the hydrogen 5 ion concentration for pH greater than 3.1." 6 You see that? 7 A. I'm sorry. I didn't see that. 8 Which paragraph we talk about here? 9 Q. At the top above, just below the 10 list of authors. 11 A. Oh, okay. That's the abstract. 12 Okay. 13 Q. And then it says: 14 "Rates increased with decreasing 15 amine basicity." 16 You see that? 17 A. I saw that, too. 18 Q. So you -- you were talking about -- 19 before about, in general, about tertiary amines? 20 A. Yeah. 21 Q. They're actually talking about 22 triethylamine here. 23 You see that they actually are 24 talking about triethylamine, right?</p>

<p style="text-align: right;">Page 270</p> <p>1 You see the word "triethylamine,"</p> <p>2 right?</p> <p>3 A. The word -- yeah. Because just now</p> <p>4 when you're reading, I didn't read the -- the</p> <p>5 abstract. I'm reading the abstract. Excuse me.</p> <p>6 (Reviews document.)</p> <p>7 Yes. Now I read that sentence.</p> <p>8 What was your question?</p> <p>9 Q. Before you were talking about</p> <p>10 tertiary amines in general and what this article</p> <p>11 means.</p> <p>12 I just was pointing out you would</p> <p>13 acknowledge they're talking about in part</p> <p>14 triethylamine. That's part of the analysis</p> <p>15 they're doing here.</p> <p>16 It's referenced there, correct?</p> <p>17 A. Yes, that -- that by reading, that's</p> <p>18 what they mention here.</p> <p>19 Q. And for the chemists at ZHP, if they</p> <p>20 had come across this or the other similar</p> <p>21 literature that points out that triethylamine can</p> <p>22 be nitrosated, as a matter of risk assessment and</p> <p>23 protecting the health and safety of patients, the</p> <p>24 reasonable thing to do would be to say, let's just</p>	<p style="text-align: right;">Page 272</p> <p>1 regarding the potential risks with using these</p> <p>2 various chemicals and found this literature, this</p> <p>3 article and similar articles in the literature</p> <p>4 that are out there, and recognized the potential</p> <p>5 nitrosation of triethylamine, the prudent thing to</p> <p>6 do would have been just to test for NDEA and NDMA</p> <p>7 just to make sure it wasn't being formed.</p> <p>8 That would be the prudent thing to</p> <p>9 do with this process that they had just developed</p> <p>10 to develop drug products to be put in people's</p> <p>11 bodies, right? That's why they're doing the risk</p> <p>12 assessment, to protect patient safety, right?</p> <p>13 Or don't you have an opinion?</p> <p>14 A. (Reviews document.)</p> <p>15 Yeah. My opinion is they really</p> <p>16 don't know this. They -- they --</p> <p>17 Q. My question assumed that if they</p> <p>18 found this literature.</p> <p>19 If they actually had done the</p> <p>20 research they didn't do and found that there's a</p> <p>21 potential creation of NDEA or NDMA, wouldn't the</p> <p>22 prudent thing to do in a risk assessment to</p> <p>23 protect the safety of patients being to do the</p> <p>24 test to see if it was producing those</p>
<p style="text-align: right;">Page 271</p> <p>1 test for nitrosamines just to make sure they're</p> <p>2 not being formed.</p> <p>3 That's the prudent thing to do,</p> <p>4 correct?</p> <p>5 MR. BERNARDO: Object to the</p> <p>6 form of the question.</p> <p>7 THE WITNESS: No, that's not.</p> <p>8 So we said you have to first -- you have</p> <p>9 to first look for nitrosamine. You know</p> <p>10 nitrosamine is a potential. That's --</p> <p>11 you made the assumption for granted,</p> <p>12 right?</p> <p>13 So we keep going back and</p> <p>14 forth. They don't have this information</p> <p>15 in their mind. Nobody ever done this,</p> <p>16 right? So they don't know this can</p> <p>17 possibly be -- be happening.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. I just asked you if -- but you're</p> <p>20 not -- you're not focusing on my question, with</p> <p>21 all due respect.</p> <p>22 If they had actually done research</p> <p>23 into the potential side effect -- rephrase.</p> <p>24 If they had done the research</p>	<p style="text-align: right;">Page 273</p> <p>1 nitrosamines?</p> <p>2 Wouldn't that be the prudent thing</p> <p>3 to do?</p> <p>4 A. Your assumption was this paper,</p> <p>5 right? So I --</p> <p>6 Q. Right.</p> <p>7 So assume for purposes of my</p> <p>8 question that they found this or similar</p> <p>9 literature alerting them to this potential risk.</p> <p>10 If they knew that potential risk,</p> <p>11 you would agree that then they should do tests to</p> <p>12 see if it happened, right?</p> <p>13 A. Well, the condition that here even</p> <p>14 if they -- like, first of all, I don't think they</p> <p>15 -- my opinion is solid, okay? I don't want to,</p> <p>16 you know, change or anything.</p> <p>17 This is they don't know there is</p> <p>18 NDEA formation. You -- you are setting the state</p> <p>19 saying, okay, they found this paper, while they're</p> <p>20 reading this paper.</p> <p>21 That's -- that's not happening,</p> <p>22 right? So they cannot find this paper.</p> <p>23 Q. I'm allowed to ask you hypothetical</p> <p>24 questions, Dr. Xue. Okay?</p>

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1 A. Okay.

2 Q. We can all agree they did no

3 research. They made no effort to learn about the

4 potential risks associated with using these

5 chemical substances. We already know that.

6 I'm asking you to assume they

7 actually did do the research and did find

8 literature that indicated that the triethylamine

9 could be nitrosated.

10 In that event, the prudent thing to

11 do as part of a risk assessment to protect patient

12 safety would be to run a test and see if it was

13 happening here, right?

14 MR. BERNARDO: Object to the

15 form of the question.

16 BY MR. SLATER:

17 Q. Wouldn't that be the smart thing to

18 do?

19 Wouldn't that have been the smart

20 thing to do because then they never would have had

21 this problem because they would have found the

22 NDEA and this never would have happened?

23 MR. BERNARDO: Object to the

24 form of the question. Calls for

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1 speculation. Assumes facts.

2 THE WITNESS: Yeah. Although

3 you said you are allowed to ask me

4 hypothetical questions, I really -- I

5 cannot answer hypothetical questions.

6 So you said the stage start

7 there and plus. So I say if you read

8 that condition, they actually talk about

9 here. They clearly say in their first

10 paragraph it's 3 to 6 and a half and that

11 there's a reason. I explain just now why

12 those can actually take place, right?

13 So and now, yes. So they --

14 when they talk about the TEA, if we

15 really want to discuss this, I need time

16 to read the whole paper. I don't

17 remember much of the detail of this

18 paper, but -- but I can tell you that by

19 just reading the -- the part, they're

20 talking about the -- the pH value is

21 greater than 3.1. That's their -- but

22 that's their study were performed.

23 BY MR. SLATER:

24 Q. So is it your opinion that when the

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1 chemists at ZHP -- well, rephrase.

2 If we assume the chemists at ZHP had

3 actually done scientific research and had actually

4 found this article, your -- your understanding of

5 their obligation in doing a risk assessment for

6 potential genotoxic impurities is to look at the

7 article and say, well, it's not describing the

8 exact conditions of our process. So we don't have

9 to worry about it and we don't have to test it.

10 Is that your understanding of what a

11 reasonable risk assessment is?

12 MR. BERNARDO: Object to the

13 form of the question. Assumes facts.

14 Argumentative. Calls for speculation.

15 THE WITNESS: Right. As I

16 said, it's a -- it's a hypothetical

17 question, right? So it's a question that

18 this paper, also the condition here, even

19 this paper describe this is not the same

20 as what they actually use in this piece

21 conditions.

22 BY MR. SLATER:

23 Q. I just said that.

24 A. Right.

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1 Q. What I asked you is: So you -- is

2 it your opinion that in doing the risk assessment,

3 the chemists should look and say, well, it's not

4 the exact conditions of our process. So we don't

5 have to worry about it and we shouldn't assess and

6 make sure there's no NDMA.

7 That's what your opinion is?

8 If you see that there's potential

9 nitrosation, if the article doesn't replicate the

10 conditions of the process, you should just say,

11 okay, nothing to worry about. We don't need to

12 test?

13 MR. BERNARDO: Same

14 objections.

15 BY MR. SLATER:

16 Q. Is that your opinion?

17 A. (Reviews document.)

18 Yeah, if I -- as you point out,

19 right? If ZHP, they happen to know this paper and

20 then they read this paper, yeah. As I said, I

21 still find this condition is -- is very different

22 or significantly different because the condition

23 they run, all these tests are different to what

24 actually the quenching process of TEA with

<p style="text-align: right;">Page 278</p> <p>1 quenching API process. I won't.</p> <p>2 Q. If the ZHP chemists --</p> <p>3 A. Uh-huh.</p> <p>4 Q. -- were aware in general that the</p> <p>5 triethylamine could be nitrosated by sodium</p> <p>6 nitrite, if they knew that in general, the prudent</p> <p>7 thing to do as part of the risk assessment to</p> <p>8 protect patient safety would be to do a test to</p> <p>9 make sure it's not creating a nitrosamine.</p> <p>10 That would be the prudent thing to</p> <p>11 do, wouldn't it be?</p> <p>12 MR. BERNARDO: Object to the</p> <p>13 form of the question. Vague.</p> <p>14 THE WITNESS: Yeah, it's</p> <p>15 hypothetic, right? So you, again, say if</p> <p>16 they know this already, but they don't</p> <p>17 know.</p> <p>18 BY MR. SLATER:</p> <p>19 Q. Well, I didn't say "if they know</p> <p>20 this already."</p> <p>21 I said if they knew of the potential</p> <p>22 for the sodium nitrite to nitrosate the</p> <p>23 triethylamine.</p> <p>24 In general, if they knew it could</p>	<p style="text-align: right;">Page 280</p> <p>1 mass production that they wouldn't need to do it</p> <p>2 either?</p> <p>3 MR. BERNARDO: Object to the</p> <p>4 form of the question. Vague.</p> <p>5 THE WITNESS: I'm not saying</p> <p>6 that. I say everything as a scientific</p> <p>7 project, we have a scope. We have based</p> <p>8 on the knowledge that we learn, we try to</p> <p>9 test the scope. What are the potentials,</p> <p>10 right? We know these are possibles.</p> <p>11 But you cannot force people to</p> <p>12 even consider the ones that to them are</p> <p>13 not possible. I think that's -- that's</p> <p>14 just not fair anymore.</p> <p>15 MR. SLATER: Let's go to</p> <p>16 another article. Let's to the</p> <p>17 theoretical investigation article.</p> <p>18 Have we shown that already or</p> <p>19 is this a new exhibit?</p> <p>20 Okay. So Exhibit I think it's</p> <p>21 12.</p> <p>22 (Document marked for</p> <p>23 identification as Xue Exhibit 12.)</p> <p>24 THE WITNESS: Can I go back?</p>
<p style="text-align: right;">Page 279</p> <p>1 happen under certain circumstances, there would be</p> <p>2 no reason for them not to do a test to make sure</p> <p>3 it wasn't happening here, correct?</p> <p>4 A. For me, I just don't see. It's like</p> <p>5 see -- you said if they say if they have the</p> <p>6 potential. I'm -- like me, I never heard about</p> <p>7 this reaction in my life before I be involved in</p> <p>8 this.</p> <p>9 If you tell me there's a potential.</p> <p>10 Every day every reaction has a potential, right?</p> <p>11 So how can I just because I hypothetically think</p> <p>12 about some potential?</p> <p>13 And if you're going to go back to do</p> <p>14 a risk assessment on every potential, again I'm</p> <p>15 running labs. I'm running project. I just don't</p> <p>16 feel that's reasonable to let my students go into</p> <p>17 the lab and running, I mean, think about any</p> <p>18 potential things that can happen. Potential.</p> <p>19 There is everything has, you know, infinitive</p> <p>20 potentials.</p> <p>21 Q. So you're saying because you</p> <p>22 wouldn't do that and you wouldn't require that in</p> <p>23 your lab, you would assume it wouldn't be required</p> <p>24 for process chemists at ZHP developing a drug for</p>	<p style="text-align: right;">Page 281</p> <p>1 MR. SLATER: You tell me,</p> <p>2 Chris. It's 12.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. So we're now going to put up as</p> <p>5 Exhibit 12, the "Theoretical Investigation --</p> <p>6 A. I'm still.</p> <p>7 Q. -- of N-nitrosodimethylamine</p> <p>8 Formation from Nitrosation of Trimethylamine."</p> <p>9 Do you see that?</p> <p>10 A. Hold on. I'm still loading.</p> <p>11 Q. Okay.</p> <p>12 A. Yes, it show up on my screen.</p> <p>13 Q. And if you look at this article,</p> <p>14 which is published in the Journal of Physical</p> <p>15 Chemistry in 2010 from the American Chemical</p> <p>16 Society, let's look at the Introduction.</p> <p>17 Can you blow it up, please?</p> <p>18 Perfect.</p> <p>19 And in the Introduction, if we go to</p> <p>20 the second paragraph. It's okay.</p> <p>21 The second paragraph says in part, I</p> <p>22 want to focus on the part that I want to talk</p> <p>23 about.</p> <p>24 In the middle of the paragraph,</p>

<p style="text-align: right;">Page 282</p> <p>1 there's a sentence that says "In addition." 2 It's about five or six lines down. 3 Do you see that? 4 "In addition to secondary amines, 5 however, a wide variety of tertiary amines have 6 also been demonstrated to react with nitrous acid 7 to produce N-nitrosamines in aqueous solutions." 8 Do you see that sentence? 9 A. Are you talking about the left 10 column? 11 Q. Yes. 12 A. Or the right? 13 Left column. You said the second 14 paragraph? 15 Q. Yes. 16 A. Okay. So I'm reading. 17 Q. In the middle of the second 18 paragraph under the Introduction on the left 19 column, it says: 20 "In addition to secondary amines, 21 however, a wide variety of tertiary amines have 22 also been demonstrated to react with nitrous acid 23 to produce N-nitrosamines in aqueous solutions." 24 Do you see that sentence?</p>	<p style="text-align: right;">Page 284</p> <p>1 sentence, right? 2 Q. Yes. 3 A. Let me see this article. 4 (Reviews document.) 5 Yeah. Under those two assumptions, 6 if I really specifically coming to look at this 7 paper, right? Which I don't think they will, 8 these people, too, because, again, there's no 9 motivation for them and this is hypothetical, 10 right? 11 But let's say if they found this 12 paper and if they read this paper, if I -- I was 13 ZHP chemist, I read this paper again. This is -- 14 I don't know whether this is same paper, but this 15 is a theoretical Investigation of -- of 16 nitrosodimethylamine from which NDMA formation 17 from nitrosation of triethylamine, right? 18 So this article tells me that, oh, 19 this paper was solely on this simple -- actually 20 structure, that's the simplest tertiary amine is 21 triethylamine. So they do some theoretical 22 investigation on this simple structure of the -- 23 the amines. That -- that -- that's really not 24 relevant to what I'm doing if I'm ZHP.</p>
<p style="text-align: right;">Page 283</p> <p>1 A. Yes, and I will read it. 2 Q. The creation of NDEA and NDMA in the 3 TEA with sodium nitrite quenching process occurred 4 in aqueous solution, correct? 5 A. Correct. 6 Q. This sentence -- well, rephrase. 7 If the science -- if the chemists -- 8 rephrase. 9 If the chemists at ZHP had come 10 across this article back when they were developing 11 or using that manufacturing process and had seen 12 that sentence, should that have been alerted them, 13 this is a potential reaction that we should risk 14 assess for to make sure it's not happening? 15 Would you at least agree with regard 16 to that sentence that would be enough to say, 17 okay, let's do a risk assessment and see if that's 18 actually occurring here? Because if it is, it's 19 not a good thing and we need to make sure it's not 20 happening? 21 A. Well, there is -- there is a quite a 22 few assumptions, right? You said if they did a 23 literature search, found this article and also if 24 they read the -- the Introduction and find this</p>	<p style="text-align: right;">Page 285</p> <p>1 And then the next thing I will be 2 caring about if you set the stage like you were 3 talking about, I -- I for some reason I just start 4 to investigate. I found this article. And that's 5 what I'm going to do is I read the -- the title, 6 right? That title is irrelevant, but if I do 7 this, I do scan. 8 I saw, okay, there is multiple 9 schemes. Talk about this hypothetic schemes that 10 these calculations was done for this particular 11 trimethylamine, which, again, it doesn't relate to 12 anything that ZHP is trying to do. 13 And then I, more importantly, if I 14 wrote down, right? If I recalculate, these 15 authors, again, didn't do any experiment to show 16 any evidence that what -- whatever they see they 17 actually hypothesize. 18 Actually, the -- so if I'm ZHP -- 19 like you said, right, I'm not against those. 20 Let's just follow what you set up the stage. 21 Although I don't agree those will happen. 22 Even if that's the case, if I'm ZHP, 23 I read. I won't pay attention because I won't 24 read the detail about what the, you know, the</p>

<p style="text-align: right;">Page 286</p> <p>1 Introduction will talk about because really there 2 are two major facts, right? 3 So their title has only a sole 4 substrate discussed in the whole paper in the 5 model establishment. Second, there's no evidence 6 from experiment at all to show any evidence any of 7 these theory is correct. 8 Q. Do you have any idea what the 9 purpose of the risk assessment was that ZHP was 10 supposed to do with regard to these two 11 manufacturing processes that developed 12 nitrosamines? Do you have any idea of what the 13 purpose of that risk assessment was? 14 A. Yes. From chemistry point of view, 15 they need to see every reagent they use what 16 the -- what the -- what the change will be caused. 17 If they -- if they change any condition in their 18 environment, in -- in their reaction conditions -- 19 like the reagent, the raw material -- they're 20 going -- they're going to check and follow all the 21 intermediate information, the yield and also the 22 impurities. Like they added things they have to 23 track down where they are. 24 Every solvent they use in any</p>	<p style="text-align: right;">Page 288</p> <p>1 situation, temperatures and also the 2 volume change as well. So you still 3 have -- have endless compounds to 4 consider. 5 So as I said, we have to 6 identify the -- the compound you want to 7 test or you want to control. Before that 8 really, you know, I think it's not 9 reasonable to expect people to -- to just 10 know everything about what they do. 11 BY MR. SLATER: 12 Q. That wasn't actually my question 13 about knowing everything in the world. 14 ZHP developed these processes to 15 manufacture pills that they were going to sell 16 commercially to patients to control their blood 17 pressure. 18 You understand that's why they were 19 developing these processes, right? So they could 20 sell pills that people would buy and take for 21 blood pressure control? 22 A. Yes. 23 Q. As part of the risk assessment, I 24 just want to know your opinion. Or if you don't</p>
<p style="text-align: right;">Page 287</p> <p>1 process, they have to track it down where they 2 are, how much they have there. So they're going 3 to do this kind of control for every single step 4 on their process. That's my understanding of risk 5 control. 6 Q. Was the risk assessment supposed to 7 take into consideration whether the reactions 8 could potentially create genotoxic impurities? 9 Was that supposed to be part of the risk 10 assessment as you know? 11 MR. BERNARDO: Object to the 12 question. Vague. Overly broad. 13 THE WITNESS: Genotoxic, as I 14 said, right, is such a broad term, right? 15 So you have to be specific. If you only 16 look at the reaction, let's say NDMA 17 formation or NDEA formation, there's 18 still endless infinitive number of 19 potential harmful compound out there, 20 even if you limit to that specific 21 process. 22 Because you still have 23 multiple reagent, multiple steps, and 24 multiple mixtures at every given</p>	<p style="text-align: right;">Page 289</p> <p>1 have an opinion. I need to know the scope of what 2 your -- your expertise goes to and what you think 3 you can draw opinions on. 4 Do you have enough of an 5 understanding of the purpose of the risk 6 assessment in terms of protecting against quality 7 or purity issues that could be dangerous to the 8 health of patients in terms of how extensive the 9 risk assessment was supposed to be? 10 Do you have any understanding of 11 that at all? 12 MR. BERNARDO: Object to the 13 form of the question. Asked and 14 answered. 15 THE WITNESS: Yeah, I'm here 16 as an organic chemistry -- chemist. I -- 17 I already explained my -- my 18 understanding about risk assessment from 19 the chemistry point of view of each 20 reaction, each reagent, each solvent they 21 use. 22 I also comment in my report 23 about what ZHP have known to actually 24 done according to those areas.</p>

<p style="text-align: right;">Page 290</p> <p>1 So in term of preparatory, we</p> <p>2 discuss earlier. I'm not qualified to</p> <p>3 comment on those.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Let's go to page 459 of this</p> <p>6 article, please.</p> <p>7 I want to go to the right-hand</p> <p>8 column, the bottom right. Just above the last</p> <p>9 paragraph.</p> <p>10 And you can see at the very bottom</p> <p>11 of the last paragraph on the right-hand column,</p> <p>12 there's a sentence that says --</p> <p>13 (Music)</p> <p>14 Looking at the last full paragraph</p> <p>15 in the right-hand column on page 459 of this 2010</p> <p>16 article, it says:</p> <p>17 "The nitrosation of secondary amines</p> <p>18 has already been extensively studied, and the DMA</p> <p>19 has been confirmed to be easily nitrosated into</p> <p>20 NDMA in an acidic nitrite solution."</p> <p>21 Do you see what I just read?</p> <p>22 A. I saw the sentence that you just</p> <p>23 read.</p> <p>24 Q. The nitrosation in the zinc chloride</p>	<p style="text-align: right;">Page 292</p> <p>1 DMA in their reaction.</p> <p>2 So I think we talk about this</p> <p>3 multiple times already, but this</p> <p>4 particular reaction I mention already.</p> <p>5 My opinion is very clear. It's</p> <p>6 documented --</p> <p>7 BY MR. SLATER:</p> <p>8 Q. Okay. Let me ask you.</p> <p>9 A. -- it's not common.</p> <p>10 Q. Sorry. I didn't mean to interrupt.</p> <p>11 A. Can I finish?</p> <p>12 Q. Yeah, go ahead.</p> <p>13 A. Yeah, but it's not common, okay?</p> <p>14 And here I think you got confused or I didn't</p> <p>15 explain myself clear.</p> <p>16 It's not this reaction is not -- is</p> <p>17 not documented. It's documented. But the fact</p> <p>18 that ZHP, they don't know anywhere in their</p> <p>19 reaction they can form DMA. Therefore, they don't</p> <p>20 have a reason to test.</p> <p>21 I want to make it clear this time.</p> <p>22 Q. Okay. You agree the reaction</p> <p>23 described in this sentence was documented in the</p> <p>24 scientific literature before they developed these</p>
<p style="text-align: right;">Page 291</p> <p>1 process occurred in an acidic nitrite solution,</p> <p>2 correct?</p> <p>3 A. The quenching process, yes.</p> <p>4 Q. If ZHP had actually done research</p> <p>5 and found this article, would you agree with me</p> <p>6 that this would have been enough to place them on</p> <p>7 notice that as part of their risk assessment, they</p> <p>8 should at least test what was being manufactured</p> <p>9 with the zinc chloride process to rule out NDMA</p> <p>10 being formed?</p> <p>11 A. I disagree with that.</p> <p>12 Q. So your opinion is that they could</p> <p>13 just ignore the potential creation of NDMA, a</p> <p>14 genotoxic impurity?</p> <p>15 MR. BERNARDO: Object to the</p> <p>16 form of the question.</p> <p>17 THE WITNESS: I disagree with</p> <p>18 -- I disagree with just what you just</p> <p>19 said because this talk about what you</p> <p>20 know. There's secondary amine</p> <p>21 specifically dimethylamine and also</p> <p>22 nitric acid, right?</p> <p>23 So, but the fact is that they</p> <p>24 don't know if they have dimethylamine or</p>	<p style="text-align: right;">Page 293</p> <p>1 processes, correct?</p> <p>2 A. I agree the reaction between DMA or</p> <p>3 secondary amine, simple secondary amine like DEA,</p> <p>4 for instance, with nitrosonium ion is documented.</p> <p>5 Q. That's all I asked.</p> <p>6 A. Right. I agree.</p> <p>7 Q. Okay. And your opinion is because</p> <p>8 ZHP didn't know that there could be DMA in the</p> <p>9 process, there was no reason for them to be</p> <p>10 concerned about this nitrosation reaction.</p> <p>11 Is that what you were just telling</p> <p>12 me?</p> <p>13 A. It's almost, right? I said, yes,</p> <p>14 what you said is part of my statement. They don't</p> <p>15 know this. Therefore, they don't know NDMA</p> <p>16 formation.</p> <p>17 The other is, I also said that for</p> <p>18 the formation of nitrosonium ion is also something</p> <p>19 not that common. It's not like when you add</p> <p>20 sodium nitrite. Everybody knows there is</p> <p>21 nitrosonium ion. Sodium nitrite doesn't equal to</p> <p>22 nitrosonium ion.</p> <p>23 I never named or -- or described</p> <p>24 sodium nitrite as a nitrosative reagent. They</p>

<p style="text-align: right;">Page 294</p> <p>1 don't know this, right?</p> <p>2 So it's -- it's there. I don't say</p> <p>3 -- I don't say it's not there, right, but it's not</p> <p>4 like everybody knows that automatically.</p> <p>5 Q. If ZHP had known of the potential</p> <p>6 for DMA to be introduced into the zinc chloride</p> <p>7 process, in that case, you would agree with me</p> <p>8 that as part of their risk assessment, it would</p> <p>9 have been prudent for them to evaluate whether</p> <p>10 NDMA was being created, right?</p> <p>11 A. Well, I won't say they must know</p> <p>12 that, right? I say this particular reaction you</p> <p>13 just read me is documented. So it's there. So as</p> <p>14 people can actually learn it, but there are two</p> <p>15 parts. One part is the DMA part. They just have</p> <p>16 no idea about it, right?</p> <p>17 So the other part is also not</p> <p>18 common. It's not like everybody learn general</p> <p>19 chemistry, go through graduate school. They all</p> <p>20 know nitrosonium ion equal sodium nitrite. They</p> <p>21 are not. You use sodium nitrite for multiple</p> <p>22 reaction as a quenching reagent. I personally</p> <p>23 never used it, but they are used, right? So I</p> <p>24 knew that, right?</p>	<p style="text-align: right;">Page 296</p> <p>1 THE WITNESS: Can you please</p> <p>2 chop your question little shorter?</p> <p>3 Because I, you know, I'm...</p> <p>4 BY MR. SLATER:</p> <p>5 Q. Number one, the chemists had to know</p> <p>6 that they were creating an acidic nitrite solution</p> <p>7 at the quenching phase, right?</p> <p>8 A. Yes, they know that.</p> <p>9 Q. Number two, they knew they were</p> <p>10 using DMF and introducing that to the zinc</p> <p>11 chloride process, correct?</p> <p>12 A. Yes, they knew they used DMF.</p> <p>13 Q. If they knew that the DMF could</p> <p>14 introduce DMA to the zinc chloride process, either</p> <p>15 as an impurity or as a degradation product, then</p> <p>16 under those circumstances, they would have been</p> <p>17 required to take the prudent step of testing to</p> <p>18 see if NDMA was being formed, correct?</p> <p>19 MR. BERNARDO: Object. Object</p> <p>20 to the form of the question. Vague.</p> <p>21 Outside the scope of his expertise.</p> <p>22 THE WITNESS: Yeah. Well, for</p> <p>23 the required part I cannot comment too</p> <p>24 much, but I'll say, right? So my --</p>
<p style="text-align: right;">Page 295</p> <p>1 So it is not -- we cannot draw a</p> <p>2 simple equation and say everybody knows that.</p> <p>3 Yeah, I recall, you know, some of the expert on</p> <p>4 the plaintiff side said that. I really cannot</p> <p>5 agree with that.</p> <p>6 Q. You would agree that the chemists at</p> <p>7 ZHP should have known that there was going to be</p> <p>8 in acidic nitrite solution at the quenching phase,</p> <p>9 right?</p> <p>10 A. Yes, because that's what they used.</p> <p>11 Q. And this article says that DMA has</p> <p>12 been confirmed to be easily nitrosated in NDMA in</p> <p>13 an acidic nitrite solution.</p> <p>14 So if ZHP had been aware of the</p> <p>15 potential for DMA to be introduced to the zinc</p> <p>16 chloride process, either as an impurity of the DMF</p> <p>17 or as a degradation product of DMF, under those</p> <p>18 circumstances, they would have been on notice as</p> <p>19 part of their risk assessment of the need to test</p> <p>20 to determine if NDMA was being formed.</p> <p>21 Do I now understand the difference?</p> <p>22 MR. BERNARDO: Object to the</p> <p>23 form of the question. The</p> <p>24 characterization of his testimony.</p>	<p style="text-align: right;">Page 297</p> <p>1 my -- my opinion state clearly. This</p> <p>2 reaction is a known reaction. It's</p> <p>3 documented. But it's not common, right?</p> <p>4 So both of the substrates are</p> <p>5 required. I said even those are there,</p> <p>6 they are not very common people will</p> <p>7 know. Because sodium nitrite you cannot</p> <p>8 just draw an equation and say it equals</p> <p>9 nitrosonium ion.</p> <p>10 And for the secondary amine,</p> <p>11 they don't know, right? So if you say,</p> <p>12 oh, they already know they have a</p> <p>13 secondary amine, then they automatically</p> <p>14 will know this reaction will take place.</p> <p>15 That's my opinion, right?</p> <p>16 So I said, yes, it's</p> <p>17 documented. This reaction is documented.</p> <p>18 People knew this. I never say this never</p> <p>19 published or nobody knows. There are</p> <p>20 publications on this particular reaction</p> <p>21 when you have the secondary amine and</p> <p>22 your nitrosonium ion. But nitrosonium</p> <p>23 ion, you need to figure out that you have</p> <p>24 nitrosonium ion.</p>

<p style="text-align: right;">Page 298</p> <p>1 And when you have those two</p> <p>2 together, you still need to have some</p> <p>3 knowledge about this reaction there to be</p> <p>4 aware there's reaction take place.</p> <p>5 Could there still be multiple</p> <p>6 stage? A chemist at ZHP has to kind of</p> <p>7 get together at the same time with the</p> <p>8 people assumption that they know there</p> <p>9 DMF contains or degrade to form DMA,</p> <p>10 which we talked about so many times that</p> <p>11 they don't know.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. The whole thought process you just</p> <p>14 walked through, ZHP never went through that</p> <p>15 thought process because they never evaluated any</p> <p>16 of this literature, any of these questions, right?</p> <p>17 MR. BERNARDO: Object to the</p> <p>18 form of the question. Vague.</p> <p>19 BY MR. SLATER:</p> <p>20 Q. Nothing you've seen, right?</p> <p>21 A. Well, I'm -- I'm here --</p> <p>22 Q. Doctor, could you just answer my</p> <p>23 question, please?</p> <p>24 ZHP never even considered what you</p>	<p style="text-align: right;">Page 300</p> <p>1 case, I have zero --</p> <p>2 Q. I'm sorry. That's not what I asked</p> <p>3 you, and I don't have unlimited time.</p> <p>4 A. Right. So you -- you ask me --</p> <p>5 Q. What you saw in the records and the</p> <p>6 documents you read --</p> <p>7 A. Uh-huh.</p> <p>8 Q. -- you saw in the materials -- new</p> <p>9 question.</p> <p>10 In the materials you reviewed, you</p> <p>11 saw no indication that anybody at ZHP thought at</p> <p>12 all about any of the things you talked about in</p> <p>13 your prior answer in terms of analyzing the</p> <p>14 literature because they never went that far to</p> <p>15 actually even look at the literature on this</p> <p>16 question, right?</p> <p>17 MR. BERNARDO: Dr. Xue, I know</p> <p>18 it's late. Just listen to what</p> <p>19 Mr. Slater is asking. He's simply asking</p> <p>20 if you've seen anything in the documents</p> <p>21 you looked at.</p> <p>22 THE WITNESS: I didn't see</p> <p>23 any documents directly showing that.</p> <p>24 MR. SLATER: I'm getting --</p>
<p style="text-align: right;">Page 299</p> <p>1 just went through. They never went through a</p> <p>2 thought process of whether or not there was an</p> <p>3 issue with any of the things you just went</p> <p>4 through.</p> <p>5 It's just something they never</p> <p>6 thought about, correct?</p> <p>7 MR. BERNARDO: Object to the</p> <p>8 form of the question. Argumentative.</p> <p>9 THE WITNESS: Yeah, I cannot</p> <p>10 speculate other people's thought. I</p> <p>11 do --</p> <p>12 BY MR. SLATER:</p> <p>13 Q. Did you see anything indicating that</p> <p>14 they thought about any of these things?</p> <p>15 A. What specific things you talk?</p> <p>16 Q. What we just talked through. That</p> <p>17 whole description you gave of the whole thought</p> <p>18 process you'd have to go through in evaluating the</p> <p>19 literature.</p> <p>20 You've seen nothing indicating that</p> <p>21 anyone at ZHP thought about any of those things,</p> <p>22 right?</p> <p>23 A. Well, I'll put it this way. If you</p> <p>24 ask me in October before I'm involved in this</p>	<p style="text-align: right;">Page 301</p> <p>1 this is probably a good time to take a</p> <p>2 break.</p> <p>3 MR. BERNARDO: Sure.</p> <p>4 THE VIDEOGRAPHER: Time right</p> <p>5 now is 4:21 p.m. We're off the record.</p> <p>6 (Recess.)</p> <p>7 THE VIDEOGRAPHER: Time right</p> <p>8 now is 4:36 p.m. We're back on record.</p> <p>9 MR. SLATER: Let's put up the</p> <p>10 deviation investigation report again,</p> <p>11 Exhibit -- which was Exhibit 5. We'll go</p> <p>12 to page 155, please.</p> <p>13 Just one second before I do</p> <p>14 this.</p> <p>15 Sorry about that.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Looking now at page 154 of this</p> <p>18 deviation investigation report, you can see the</p> <p>19 middle of the page:</p> <p>20 "Test Result of Triethylamine</p> <p>21 Hydrochloride Samples by Huahai."</p> <p>22 You see that?</p> <p>23 A. So you talk about the page 155.</p> <p>24 Q. I said 154.</p>

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1 A. Oh, I'm sorry. 154.
2 You said there is what?
3 Q. On page 154 in the middle of the
4 page, you'll see it says number 4?
5 A. Right.
6 Q. In the middle of the page, it says
7 number 4) "Test Result of Triethylamine
8 Hydrochloride Samples by Huahai."
9 You see that?
10 A. Yes. But can you please make it
11 bigger? Thank you.
12 Q. Okay.
13 A. That's great.
14 Q. It then says analytical -- well,
15 rephrase.
16 It says:
17 "Analytical method for DEA and DMA
18 and Triethylamine Hydrochloride was developed by
19 Huahai, and the Triethylamine Hydrochloride (from
20 Kente Catalytic materials Co., Ltd) in stock was
21 analyzed. The DMA and DEA results obtained was in
22 Table 4-30 as follows."
23 You see that table below?
24 A. You talk about Table 4-30.

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1 Q. You see it right there in front of
2 you?
3 A. Yeah, yeah. Okay. Yeah.
4 Q. First of all, triethylamine
5 hydrochloride, was that used in the TEA with
6 sodium nitrite quenching process?
7 A. I'm sorry. Your -- your voice was
8 chopped off just now. I just heard the word
9 "process" just now.
10 Q. Was triethylamine hydrochloride used
11 in the TEA with sodium nitrite quenching process?
12 A. Yes. Yes.
13 Q. That's what we've been referring to
14 as triethylamine, right?
15 A. Yes.
16 Q. And you can see that they tested for
17 DEA and DMA and they found DEA at 106.3 parts per
18 million.
19 You see that?
20 A. I saw that from the table that you
21 show.
22 Q. Let's go to the next page. Well,
23 actually, let's stop there for a second. I didn't
24 mean to jump that quickly.

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1 So this is -- rephrase.
2 This is ZHP confirming that the
3 triethylamine hydrochloride they used in that
4 process contained as an impurity DEA, correct?
5 MR. BERNARDO: Object to the
6 form of the question. Vague.
7 THE WITNESS: So what I can
8 read from this table is for this batch
9 number -- I don't need to read the
10 number -- I think they tested for DMA and
11 DEA.
12 Can we know what LOD -- LOD
13 for limit?
14 BY MR. SLATER:
15 Q. Level of detection.
16 A. Level of detection. Okay.
17 So I can read that for DMA for
18 whatever method they are using to detect this,
19 it's already below that. So I think the -- the
20 level set for the detection was 45 ppm. And then
21 with DEA, their detect result for this batch was
22 actually 106.3 ppm. That's it.
23 Q. You would agree with me that ZHP was
24 purchasing triethylamine hydrochloride to use in

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1 the manufacturing process for valsartan.
2 You would agree that under those
3 circumstances, ZHP should have known of the
4 potential impurities in that product that they
5 were going to include in their process?
6 MR. BERNARDO: Object to form
7 of the question. Vague.
8 BY MR. SLATER:
9 Q. Or were they allowed to just be
10 ignorant of the impurities that might be
11 introduced into the process and not worry about
12 it?
13 MR. BERNARDO: Object to the
14 form of the question. Vague.
15 Argumentative.
16 THE WITNESS: I disagree with
17 what you just said.
18 BY MR. SLATER:
19 Q. Okay. You disagree. That's fine.
20 Let me ask the question differently.
21 Did ZHP need to know if there was a
22 substance it was going to introduce into its
23 manufacturing process, if that substance had
24 impurities that could be introduced into the

<p>Page 306</p> <p>1 process? Did they have to know whether or not 2 that could happen?</p> <p>3 MR. BERNARDO: Object to the 4 form of the question. Vague.</p> <p>5 BY MR. SLATER:</p> <p>6 Q. Yes, no, or you have no opinion.</p> <p>7 A. I don't think I'm clear about what 8 you asking. You are saying --</p> <p>9 Q. I'll be even more clear. 10 ZHP was using triethylamine 11 hydrochloride to manufacture valsartan, right?</p> <p>12 A. That's correct.</p> <p>13 Q. As shown here on this deviation 14 investigation report from ZHP, triethylamine 15 hydrochloride has DEA as an impurity in the 16 commercially sold form of that substance.</p> <p>17 You see that? That's what this 18 document is showing, right?</p> <p>19 MR. BERNARDO: Object to the 20 form of the question. Vague. 21 Characterization of the document.</p> <p>22 THE WITNESS: Well, as the 23 document was -- was looking backward from 24 2018, right? So they knew already at</p>	<p>Page 308</p> <p>1 here in their report is that, okay, so 2 the DMA possibly not. If there is, it's 3 definitely below their -- their -- their 4 LOD. And they did find DEA in the -- 5 they come, you know, in the triethylamine 6 sample, the particular batch that they 7 use for this, right?</p> <p>8 So I think that this is very 9 logic, right? So I don't see if there 10 are any questions because we -- they did 11 what they did.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. You literally just told me what the 14 document shows and that is not -- I didn't ask you 15 to explain to me what the document shows. We 16 already went through that. So I'm going to try 17 the question again.</p> <p>18 Should ZHP -- well, first of all, 19 let me ask you a foundational question.</p> <p>20 A. Sure.</p> <p>21 Q. You agree that it's more likely than 22 not that the triethylamine hydrochloride that ZHP 23 used in the TEA with sodium nitrite quenching 24 process contained DEA as an impurity when they</p>
<p>Page 307</p> <p>1 this moment when they actually do this 2 analysis where in their -- in their 3 process DMA was formed. And then as you 4 read in the last section there, they also 5 have emphasize the reason why it can 6 happen, right?</p> <p>7 So they have the dimethylamine 8 as a reactant. They said somewhere on 9 the process there might be dimethylamine 10 there. They also there, the other part, 11 nitrosonium ion somewhere on this process 12 you can form.</p> <p>13 They say when these two 14 together, when they meet in the reaction 15 vessel, they can possibly form. That's 16 what they actually hypothesize.</p> <p>17 Here is what they actually 18 show. After they know, okay? In my 19 process in PA with quenching, I saw NDEA. 20 And then I start to track it back to see, 21 okay, what -- whether there's actually, 22 you know, they're basically hunting down 23 where the DEA actually come from.</p> <p>24 So what they found and report</p>	<p>Page 309</p> <p>1 actually were manufacturing valsartan.</p> <p>2 Do you agree? Yes, no, or you have 3 no opinion.</p> <p>4 A. I cannot agree because we have to 5 set the -- set the scope, right?</p> <p>6 Q. You said, no, you don't agree.</p> <p>7 Okay.</p> <p>8 A. So this -- this table tells us for 9 this particular batch --</p> <p>10 Q. I'm not asking about this table, 11 Doctor, and I don't have unlimited time. So I 12 just need you to answer my question.</p> <p>13 I'm asking a very straightforward 14 question. Look at me maybe, not at the document 15 maybe we will -- because you're focused on the 16 document. I'm trying to ask you a question not 17 about the document now. Okay?</p> <p>18 I'm asking about ZHP when they 19 developed and used the manufacturing process.</p> <p>20 Okay?</p> <p>21 A. Uh-huh. Yes.</p> <p>22 Q. That's the time frame.</p> <p>23 During that time, in your opinion, 24 did the triethylamine that was utilized contain</p>

<p style="text-align: right;">Page 310</p> <p>1 DEA as an impurity already before it was inserted 2 into the manufacturing process? 3 Either your opinion is yes, it was 4 there, no, it wasn't there, or "I don't have an 5 opinion." That's what I'm asking you. 6 A. So you ask my opinion whether I 7 believe the TEA catalyst they use in their TEA 8 process with quenching contained an impurity DEA, 9 right? So, but you ask me this question today. 10 Q. Why don't you just answer the 11 question, please, instead of giving me a speech. 12 A. I really can't because you ask me 13 today. I, of course, know now based on the data 14 they look backward. They showed, yes, there is, 15 but that doesn't really solve the puzzle, right? 16 So they don't know before and they are not -- they 17 are not looking at that time when they develop 18 for -- 19 Q. Doctor, I'm sorry to interrupt you, 20 but I didn't ask you about what they were looking 21 for. I asked if you had an opinion as to whether 22 it was there. 23 You just told me, in your opinion, 24 yes, there was DEA in the triethylamine.</p>	<p style="text-align: right;">Page 312</p> <p>1 less than the level of detection 45 parts per 2 million." 3 We just looked at that, correct? 4 That's what we just looked at on the prior page? 5 That's what I just showed you. 6 A. Yes. 7 Q. Okay. The next sentence says: 8 "However, DMA was detected in one 9 batch of Triethylamine Provided by Zhejiang Jianye 10 Chemicals Company Limited. The result is in Table 11 4-31 as follows." 12 So you can see they have 13 Triethylamine Test Results down below from a 14 different manufacturer. 15 Do you see that? 16 A. You talk about Table 4 dash? 17 Q. Table 4-31. It's literally there 18 right there on the screen. 19 A. Okay. 20 Q. Do you see that they tested that 21 triethylamine that they purchased from this 22 manufacturer, Zhejiang Jianye Chemicals Company 23 Limited, and they gave the results in that table. 24 You see the results in front of you,</p>
<p style="text-align: right;">Page 311</p> <p>1 A. I -- 2 Q. I didn't ask you about their 3 research. I asked you one question. I don't have 4 unlimited time. So I need you to just answer the 5 questions I'm asking, please. 6 A. My answer is, when I look at now, 7 yes, they have the TEA in there. But this is 8 looking backward when they actually figure out. 9 They don't know whether they have it. My -- if 10 you want me a yes or no -- 11 Q. I literally didn't ask you if they 12 knew it was there. I asked what your opinion was 13 as to whether it was there. I don't understand 14 why you persist in giving me speeches about things 15 I'm not asking you, sir. 16 Let's go to the next page, page 155. 17 If you go to the middle of the page. 18 Scroll down so we can get the whole middle. Right 19 there, yeah. 20 Looking at the middle of page 155 of 21 this deviation investigation report from ZHP, it 22 says: 23 "The results indicate the presence 24 of DEA in Triethylamine Hydrochloride, and DMA was</p>	<p style="text-align: right;">Page 313</p> <p>1 correct? 2 A. I do see the table saying for three 3 batches this time, right? 4 Q. You can see for one batch they 5 actually had 8.2 parts per million of DMA. 6 You see that? 7 A. Sorry. What was the LOD for this 8 one? 9 Q. Level of detection. I don't know. 10 I'm sorry. 11 Can you just answer the question, 12 please? 13 My question again is: If you look 14 at the table, it shows the results for testing for 15 DMA and DEA as impurities of the triethylamine 16 from this manufacturer. 17 You see that in front of you, 18 correct? 19 A. I do see that number. But can I 20 ask? Because the last LOD was 45. I just 21 curious. Because every experiment has errors, 22 right? So -- 23 Q. Don't know. I only know what the 24 report says. This is all I know is what's right</p>

<p style="text-align: right;">Page 314</p> <p>1 in front of you.</p> <p>2 A. Yeah, I can read those numbers. I'm</p> <p>3 with you on those numbers.</p> <p>4 Q. So it shows that -- it shows in the</p> <p>5 first batch, which is the last three digits are</p> <p>6 013, it had DMA of 8.2 parts per million and DEA</p> <p>7 of 85.3 parts per million.</p> <p>8 That's documented, right?</p> <p>9 A. That is the numbers are correct,</p> <p>10 but, again, I want to -- if as a scientist --</p> <p>11 Q. I'm just asking you if you can see</p> <p>12 the numbers in front of you.</p> <p>13 Is that what the numbers say?</p> <p>14 A. Yeah, I can see the numbers.</p> <p>15 Q. The second batch 014, it said that</p> <p>16 no DMA was detected. That's what ND says, not</p> <p>17 detected. And it had DEA of 28.6 parts per</p> <p>18 million.</p> <p>19 Do you see that?</p> <p>20 A. I see the two as you read.</p> <p>21 Q. And the third batch 015, for DMA it</p> <p>22 says ND, not detected, and for DEA 26.1 parts per</p> <p>23 million.</p> <p>24 You see that?</p>	<p style="text-align: right;">Page 316</p> <p>1 A. Okay.</p> <p>2 Q. -- do you see any indication during</p> <p>3 that time period that anyone at ZHP realized that</p> <p>4 DEA was an impurity in the triethylamine that they</p> <p>5 were using? Yes or no.</p> <p>6 A. I cannot comment on that. I</p> <p>7 don't -- I don't -- I don't read anything about</p> <p>8 it. I didn't see any evidence about that.</p> <p>9 Q. You would agree with me that it was</p> <p>10 well-documented in the literature for somebody who</p> <p>11 was a chemist who actually was doing a rigorous</p> <p>12 scientific literature search as part of a risk</p> <p>13 assessment for a drug manufacturing process, if</p> <p>14 they looked, they would have been able to find the</p> <p>15 literature saying that under the conditions of</p> <p>16 that process, the sodium nitrite and the processes</p> <p>17 that were happening could potentially nitrosate</p> <p>18 the DEA and create NDMA.</p> <p>19 You would agree that that</p> <p>20 information was out there if they had looked,</p> <p>21 correct?</p> <p>22 MR. BERNARDO: Object to the</p> <p>23 form of the question. Compound.</p> <p>24 Argumentative.</p>
<p style="text-align: right;">Page 315</p> <p>1 A. Yes.</p> <p>2 Q. Now, my question is this: Based on</p> <p>3 the fact that there was DEA impurity in the</p> <p>4 triethylamine -- well, let me ask you this, first</p> <p>5 of all.</p> <p>6 Did you see any indication that</p> <p>7 anyone at ZHP actually noticed that there was DEA</p> <p>8 as an impurity of the triethylamine they used in</p> <p>9 the TEA with sodium nitrite process?</p> <p>10 My question is: Of everything you</p> <p>11 looked at, did anybody at ZHP ever realize that?</p> <p>12 That's my first question. Did you</p> <p>13 see anything to that effect?</p> <p>14 A. So you're asking --</p> <p>15 Q. That's the question.</p> <p>16 A. You're asking the data that we show</p> <p>17 here in this table --</p> <p>18 Q. No, I'm not asking about this data.</p> <p>19 I'm asking: Did anybody from ZHP</p> <p>20 back when they were manufacturing the valsartan</p> <p>21 with the sodium nitrite with TEA -- rephrase.</p> <p>22 Back when ZHP was developing and</p> <p>23 using the TEA with sodium nitrite quenching</p> <p>24 process --</p>	<p style="text-align: right;">Page 317</p> <p>1 Go ahead.</p> <p>2 THE WITNESS: I disagree.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. Fine. You disagree.</p> <p>5 Do you disagree because it's your</p> <p>6 opinion that unless there's an article that</p> <p>7 replicates the exact conditions of the process</p> <p>8 that they intended to use, they don't have to</p> <p>9 think about it as a potential issue?</p> <p>10 A. No, I never said that.</p> <p>11 I use the general practice of -- of</p> <p>12 science, right? So every science has a scope,</p> <p>13 right? You cannot just artificially expand your</p> <p>14 scope of your understanding by saying this or that</p> <p>15 is for sure, everybody knows.</p> <p>16 I -- my approach is rely on the</p> <p>17 reference and what's available. So I did my</p> <p>18 search. I found for -- for the secondary amine</p> <p>19 reaction, if you know there's a secondary amine,</p> <p>20 it's documented. But it's not as common as the</p> <p>21 expert of the plaintiffs claim.</p> <p>22 And for the tertiary amine, it's --</p> <p>23 it's much more complicated. I didn't know my</p> <p>24 personally. I never teach. I never really do any</p>

<p style="text-align: right;">Page 318</p> <p>1 research before I'm involved in this case. 2 By reading more recent papers 3 discuss about this, I have no clue about this 4 reaction. So that's how I form my opinion. 5 I mean, these batches as you showing 6 here, they shows, yes, these batch when they look 7 back, they did find DEAs in their multiple 8 batches. 9 I just don't see why this will help 10 them to actually figure out because this 11 everything they did here -- they did here is 12 backward. We now sitting 2023 talking about this 13 happening 2003. 2013. I'm sorry. 14 Q. DEA is a secondary amine, right? 15 A. DEA is dimethylamine. It is a 16 secondary amine. 17 Q. And it was well-documented in the 18 literature that a secondary amine could be 19 nitrosated, correct? 20 MR. BERNARDO: Object to the 21 form of the question. Vague. 22 BY MR. SLATER: 23 Q. During the entire time they 24 developed and used these processes, it was</p>	<p style="text-align: right;">Page 320</p> <p>1 MR. BERNARDO: Wait, Dr. Xue. 2 Object to the form of the 3 question. Asked and answered. Assumes 4 facts. Vague. Compound. 5 Go on. 6 THE WITNESS: That's not 7 correct. 8 BY MR. SLATER: 9 Q. Okay. What this -- 10 A. You have a lot of hypothetical 11 situation added in there. I cannot really answer 12 question with so many hypothesis. I already state 13 my opinion clearly about these two situations. 14 MR. SLATER: Okay. Let's -- 15 let's look at this, too. Just -- let's 16 go to the next document. 17 (Document marked for 18 identification as Xue Exhibit 13.) 19 THE WITNESS: Now is this 14, 20 12 or 13? 21 MR. SLATER: What number is 22 this? 13. 23 THE WITNESS: Hold on. I'm 24 still loading. I only see 12.</p>
<p style="text-align: right;">Page 319</p> <p>1 well-documented in the literature that a secondary 2 amine could be nitrosated, correct? 3 A. As I said -- 4 Q. You said that, right? 5 A. I said that secondary amine can be 6 nitrosated. It's documented, right, multiple 7 times. But I said -- 8 Q. That's all I asked you, Doctor. I 9 didn't ask for another speech. I asked if it was 10 well-documented. You agreed. We're fine. 11 A. No, I said it's documented. I never 12 said it's well-documented. 13 Q. Okay. It's documented. 14 A. Thank you. 15 Q. If ZHP had actually done a 16 literature search, found the literature 17 documenting that a secondary amine could be 18 nitrosated, and they had then said, well, since 19 this could potentially happen in general, let's 20 test for NDMA and they used mass spectrometry, 21 they would have been able to find the NDMA. 22 Is that correct? Yes, no, or you 23 have no opinion? 24 A. That --</p>	<p style="text-align: right;">Page 321</p> <p>1 BY MR. SLATER: 2 Q. It's only one page. It's the page 3 on the screen. That's the whole exhibit. 4 A. Yeah, I can see the page on the 5 screen. 6 Q. All right. Just what we did is, we 7 found on the Internet this Certificate of Analysis 8 from the same company that was discussed in that 9 Table 4.31 we just went through, and you can see 10 it's dated November 25, 2012 just above the table. 11 And you can see that it shows the 12 triethylamine analysis showed that there was 13 diethylamine in that product. 14 Do you see that? 15 A. So I never see this document before. 16 Q. Do you see that it shows that there 17 was diethylamine noted in the Certificate of 18 Analysis for the triethylamine sold by this 19 manufacturer? 20 I'm literally just asking you do you 21 see that it documented the presence of 22 diethylamine. 23 A. I saw this. So there's entry. 24 Because I have to -- because I never seen it</p>

<p style="text-align: right;">Page 322</p> <p>1 before, I need to understand what this document 2 is, right? I think that that's reasonable, right? 3 So -- so there is an entry talk 4 about diethylamine. 5 So what "WT" stand for? 6 Q. I'm guessing percentage by weight, 7 but you're the scientist. I'm the guy who failed 8 those science classes. 9 A. Well, yeah. So I think that that's 10 a number that I need to know what -- what that 11 means. 12 Q. Okay. 13 A. I think that's a good guess, but I 14 really don't know what that is. 15 Q. Okay. Does that prevent you from 16 saying that you can see that -- 17 A. No. No. 18 Q. -- triethylamine they found that 19 there was diethylamine in the triethylamine? 20 It's there, right? You see it on 21 the page, right? 22 A. Well, because -- 23 Q. Doctor, do you see it on the page? 24 I'm not asking for an explanation</p>	<p style="text-align: right;">Page 324</p> <p>1 you to give you any Certificate of Analysis that 2 they had for the DMF or the triethylamine that was 3 used by ZHP? 4 A. Well, early on I said -- 5 Q. Doctor, it's a simple question. 6 Did you ask for a Certificate of 7 Analysis from the lawyers or not? 8 A. I didn't -- I didn't ask for those. 9 Q. All right. Did you see any? 10 A. Sorry. You're -- you're freezing 11 for a second. 12 Q. Did you see any? 13 A. What? What? Any of what? 14 Q. Did you see any Certificate of 15 Analysis for the DMF or triethylamine used by ZHP? 16 Yes or no. 17 A. I don't remember seeing any. 18 Q. Okay. Take that down. 19 Now what we're going to do is, we're 20 going to go to some pages within the DMF, the drug 21 master file that was filed with the FDA, and it's 22 the section on impurities. The module on 23 impurities. 24 And we're going to go to page --</p>
<p style="text-align: right;">Page 323</p> <p>1 for all the reasons that you want to tell me it 2 doesn't matter. It's a simple question. So I'll 3 try it cleanly. 4 On this Certificate of Analysis 5 dated November 25, 2012, for the chemical company 6 that was discussed in the deviation investigation 7 report in Table 4.31, you can see that it 8 documents the presence of diethylamine. 9 You see that, right? 10 MR. BERNARDO: Objection. 11 Form. 12 THE WITNESS: I see 13 diethylamine there. I'm sorry. 14 BY MR. SLATER: 15 Q. Okay. Did you ever ask anybody to 16 give you any Certificate of Analysis from any of 17 the suppliers or manufacturers for the DMF or 18 triethylamine that was used in the manufacturing 19 processes for valsartan? 20 Did you ask for those documents? 21 That's all I'm asking you. 22 A. Can you repeat again? Because your 23 sentence very long. I got lost in the middle. 24 Q. Did you ask the lawyers who hired</p>	<p style="text-align: right;">Page 325</p> <p>1 A. Hold on. We talk about a new 2 exhibit -- exhibit like 14? 3 Q. We're going to go to page 100 and -- 4 A. I'm not seeing that yet in my 5 folder. 6 Q. It's just not there yet, Doctor. 7 A. Okay. I'm sorry. 8 Q. Chris is doing it right now. 9 A. Thank you for reminding me. 10 Q. No problem. 11 Let's go to page 147 of 172 first. 12 A. Please give me a second because I'm 13 still refreshing. 14 Q. It's okay. I'm just letting him 15 know where he's going. No problem. 16 (Document marked for 17 identification as Xue Exhibit 14.) 18 BY MR. SLATER: 19 Q. I'm looking at page 147 of 172. It 20 says "Discussion about Genotoxicity." 21 Do you see that? 22 A. Hold on. Give me a second. I'm 23 still loading and trying to open this. 24 You said 147?</p>

<p style="text-align: right;">Page 326</p> <p>1 Q. It's on the screen, Doctor.</p> <p>2 A. Yeah, yeah. Because can you --</p> <p>3 MR. SLATER: Help me out,</p> <p>4 Rich, please.</p> <p>5 MR. BERNARDO: He's entitled</p> <p>6 to take a look at the document, not the</p> <p>7 page that you have on the screen, Adam.</p> <p>8 MR. SLATER: Okay. Well,</p> <p>9 that's okay. We're going to have to</p> <p>10 start talking about time issues if we get</p> <p>11 into them because this has been very,</p> <p>12 very difficult.</p> <p>13 THE WITNESS: Yes, I can see</p> <p>14 this page now.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. Great.</p> <p>17 This is the section with a</p> <p>18 "Discussion about Genotoxicity."</p> <p>19 Let's now go to the next page, 148</p> <p>20 of 172. It says "Discussion on Impurities" at the</p> <p>21 top of the page. And then it has -- it says</p> <p>22 "Organic impurities."</p> <p>23 "All the potential organic</p> <p>24 impurities are demonstrated in Valsartan listed as</p>	<p style="text-align: right;">Page 328</p> <p>1 Q. It says in part that there's no high</p> <p>2 potency genotoxic group, such as aflatoxin-like-,</p> <p>3 N-nitroso-, and azoxy-compound in impurities for</p> <p>4 the zinc chloride valsartan.</p> <p>5 Do you see that?</p> <p>6 MR. BERNARDO: Object to the</p> <p>7 form of the question and the</p> <p>8 characterization of what the document</p> <p>9 says.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. You see what I just read, right?</p> <p>12 A. I saw what you just read.</p> <p>13 Q. Okay. That was an untrue statement</p> <p>14 because there was actually NDMA in the valsartan</p> <p>15 manufactured with the zinc chloride process,</p> <p>16 right?</p> <p>17 MR. BERNARDO: Object to the</p> <p>18 form of the question.</p> <p>19 THE WITNESS: I need to read</p> <p>20 the -- this table a little bit because I</p> <p>21 don't remember seeing this.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Doctor, it's a very simple question.</p> <p>24 When they -- when ZHP represented</p>
<p style="text-align: right;">Page 327</p> <p>1 follows."</p> <p>2 Do you see that?</p> <p>3 A. Yes. At the table, right?</p> <p>4 Q. Okay. And then let's go to the</p> <p>5 bottom of the table to the language there. And in</p> <p>6 the last paragraph, it says:</p> <p>7 "Regarding the impurity D through J</p> <p>8 and hydrolysis product, there is not any high</p> <p>9 potency genotoxic group, such as, aflatoxin-like-,</p> <p>10 N-nitroso-, and azoxy-compound has been included</p> <p>11 in these impurities. And these impurities are</p> <p>12 demonstrated absence in the drug substance and</p> <p>13 controlled within the any unknown impurity of NMT</p> <p>14 0.10% in the final product. These impurities are</p> <p>15 no genotoxic risk in Valsartan."</p> <p>16 Do you see what I just read?</p> <p>17 A. Sorry. There's airplane noise. Can</p> <p>18 you guys hear the noise?</p> <p>19 Q. Do you see the last paragraph on the</p> <p>20 page I just read?</p> <p>21 A. I do see the last paragraph, but I</p> <p>22 didn't quite follow your -- your -- your reading</p> <p>23 because the noise outside. I can read that</p> <p>24 paragraph myself, though.</p>	<p style="text-align: right;">Page 329</p> <p>1 that there were no N-nitroso-compounds, it was --</p> <p>2 that was not accurate because there was NDMA in</p> <p>3 the valsartan produced with the zinc chloride</p> <p>4 process, correct?</p> <p>5 MR. BERNARDO: Object to the</p> <p>6 form of the question and how you just</p> <p>7 mischaracterized the document. And he</p> <p>8 asked to read it to see what the other</p> <p>9 reference was referring to. So give him</p> <p>10 a minute to see that.</p> <p>11 BY MR. SLATER:</p> <p>12 Q. Take a look.</p> <p>13 A. (Reviews document.)</p> <p>14 So this document is very big. I</p> <p>15 recall when I first load the document, there's</p> <p>16 some structures. I want to see the structure of</p> <p>17 the drugs. Are they anywhere in the document?</p> <p>18 Q. Doctor, I asked you a specific</p> <p>19 question.</p> <p>20 Are you now looking to find out if</p> <p>21 they disclosed the presence of NDMA? I mean --</p> <p>22 A. No, no, no.</p> <p>23 Q. -- a different copy?</p> <p>24 A. I'm asking because they talk about</p>

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1 this structure G, H, and all the --

2 Q. It's right above. It's on the same

3 page directly above the language. It's that table

4 right above it.

5 MR. SLATER: Scroll down a

6 little so he can see it.

7 THE WITNESS: Yeah, I -- I --

8 MR. SLATER: Chris, please.

9 THE WITNESS: What the page

10 number again for this? I went back to

11 the first page. I need to go back.

12 BY MR. SLATER:

13 Q. Right there in front of you on the

14 screen. 148. That's literally the table that's

15 being referred to.

16 A. 148. I'm -- okay. So I'm on 148.

17 So the reading of this second

18 paragraph that you just read to me regarding to

19 the impurity D through J, N is hydrolysis

20 products, okay? Those -- those compounds.

21 All right. So what they describe is

22 these compound structure doesn't actually has any

23 of those listed functionalities including nitroso

24 was in the structure, right?

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1 So, and, therefore, they are not --

2 they are not qualified as high, you know, toxic

3 compound because they don't have any of those

4 three structures -- groups. And because of that,

5 they are saying they are not quantified --

6 qualified as high potency genotoxic groups.

7 And then they say these impurities

8 are -- are -- their -- their presence is actually

9 within the controlled NMT -- I don't know what NMT

10 stands for -- but within the controlled relation.

11 Therefore, they say there's no genotoxic risk.

12 I don't -- I don't see if there's

13 any problem because they -- these structures, as I

14 saw on the first page of the document, they have

15 none of this containing these listed

16 functionalities. Therefore, they are not high

17 risk and presumably the non-high risk compound has

18 a limit of .10 percent.

19 Now, they are all okay. That's what

20 they talk about here.

21 Q. All right. Did they -- did ZHP do

22 any testing for NDMA or NDEA, or any other

23 nitrosamine that you've seen, for the valsartan

24 manufacture with the zinc chloride process at any

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1 time before 2018 testing?

2 A. Before 2018, I didn't see any

3 evidence. Because they -- as my opinion, they

4 don't have any clue and they don't have any reason

5 to test. But after, yes, we believe especially at

6 the end of the day, they have the root cause

7 analysis to see what is the possible reason. They

8 raise hypothesis.

9 Q. Okay. We're going to take that

10 down.

11 You talked in your report about the

12 July 27, 2007 e-mail sent by Jinsheng Lin to Min

13 Li and others.

14 Do you recall writing about that in

15 your report?

16 A. I -- I do.

17 Q. All right. Did you read Min Li's

18 testimony in his deposition where he talked about

19 what the e-mail said?

20 A. Well, I -- I read depositions from

21 multiple people. I definitely read Min Li's

22 deposition, but I don't know whether I read every

23 single line of that.

24 By the way, are you -- are you going

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1 to sent out another file which I don't see?

2 Q. I don't know. I haven't decided

3 yet.

4 A. Oh, okay.

5 Q. Not sure.

6 Did you read Min Li's testimony

7 where he testified to what the e-mail said?

8 MR. BERNARDO: Object to the

9 form of the question. Asked and

10 answered.

11 THE WITNESS: As I said, if

12 you, you know, if you have a document,

13 I'd like to see it because then we both

14 are clear what we talk about here.

15 BY MR. SLATER:

16 Q. I'm talking about the deposition of

17 Min Li.

18 A. Right.

19 Q. Did you read the part where he told

20 us under oath, speaking for ZHP as a corporate

21 representative, what the e-mail said?

22 MR. BERNARDO: Object to the

23 form of the question. If there's a

24 portion of the testimony you're asking if

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1 he's read, it would be helpful to show
2 him.

3 THE WITNESS: I -- I read
4 from Min Li's testimony, but I really
5 don't know what line or what section you
6 refer to. It's hard for me to -- to
7 actually speculate.

8 BY MR. SLATER:
9 Q. I'm looking at your report. Why
10 don't we look at your report. You have your hard
11 copy of your report right there. Let's go to page
12 54.

13 You see your report page 54? You
14 have that in front of you?

15 A. Yes.

16 Q. Okay. And right in the middle of
17 the page Section VII, you say in the first
18 sentence that:

19 "Plaintiffs' experts assert that, in
20 an e-mail dated July 27, 2017, ZHP employee
21 Jinsheng Lin 'acknowledged the impurity he was
22 investigating [in crude irbesartan] was very
23 likely an 'N-NO compound' which 'is similar to the
24 N-nitrosodimethylamine that occurs in valsartan

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1 when quenched with sodium nitrite."
2 Do you see that?

3 A. I saw that quote.

4 Q. And did you read the actual e-mail?

5 A. I -- I -- I read the e-mail. I
6 would -- I think the e-mail if you -- the e-mail
7 was in both Chinese and then English like a
8 version.

9 Yeah, I remember reading the e-mail.

10 Q. Okay. And you say in your report on
11 page 55:

12 "Mr. Lin's e-mail is written in
13 Chinese, my native language."

14 So then you say:

15 "Based on my understanding of
16 Chinese and my expertise as a chemist" and then
17 you go on.

18 So the question I want to ask you
19 is: In terms of your interpretation of the
20 e-mail, you're relying on your reading of the
21 document in Chinese and your expertise as a
22 chemist in order to interpret it, correct?

23 A. Well, not just that. I also
24 considered the translate -- translates I got from

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1 the counsel.

2 Q. Did you also consider Min Li's
3 testimony as to what the e-mail actually said when
4 he was deposed under oath as a corporate
5 representative speaking for ZHP?

6 MR. BERNARDO: Object to the
7 form of the question. Vague.

8 THE WITNESS: So, yeah. So
9 it's better that you highlight what he
10 said. I remember reading his
11 testimonies, but I don't know what
12 section you refer to.

13 BY MR. SLATER:
14 Q. Well, you didn't actually --
15 rephrase. Hang on.

16 You actually didn't talk in your --
17 rephrase.

18 You didn't actually quote what
19 Dr. Li said in his testimony, right? That's not
20 quoted in your report, right?

21 A. I didn't.

22 Q. When you interpreted what the e-mail
23 said, did you rely on your own reading of the
24 e-mail, or did you rely on Dr. Li's reading of the

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1 e-mail which he testified to under oath on behalf
2 of ZHP?

3 MR. BERNARDO: Object to the
4 form of the question. Vague.

5 THE WITNESS: I mean, for
6 this e-mail, I read in different format,
7 right? They all be kind of different.
8 And then I -- what I read, truthfully,
9 what I did is, I went in to see what the
10 whole article -- what the whole document
11 was really talk about in science.

12 Because I, you know, I'm an
13 organic chemist. I want to learn because
14 there are confusions. I have to admit
15 there are confusions for me. I don't
16 really understand some part of this in
17 detail.

18 So I just went in as a
19 scientist to see what the science told
20 me. And then I also, you know, I
21 remember that e-mail also had -- had a --
22 had an attachment in there.

23 I -- I specifically asked the
24 counsel to provide that attachment to me.

<p style="text-align: right;">Page 338</p> <p>1 I also read that attachment. I</p> <p>2 believe -- I might be wrong in this. But</p> <p>3 I believe the attachment only -- I don't</p> <p>4 remember reading in Chinese. Probably I</p> <p>5 only read English. I might be wrong on</p> <p>6 that.</p> <p>7 But, anyway, so my -- my -- my</p> <p>8 -- my opinion was formed solely just</p> <p>9 based on my understanding of the</p> <p>10 chemistry of the two full document</p> <p>11 together to reach to the conclusion.</p> <p>12 I don't remember quoting</p> <p>13 anybody because I, you know, I don't want</p> <p>14 to kind on anybody side. I just want to</p> <p>15 see what the science taught me about.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. Were you aware when you formed your</p> <p>18 opinion about what the e-mail said and meant that</p> <p>19 Dr. Li's testimony as a corporate representative</p> <p>20 of ZHP was binding on ZHP?</p> <p>21 MR. BERNARDO: Object to form.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. Were you aware of that?</p> <p>24 MR. BERNARDO: Object to the</p>	<p style="text-align: right;">Page 340</p> <p>1 that it is binding, which is legal.</p> <p>2 MR. SLATER: Do you want to</p> <p>3 take the position that your corporate</p> <p>4 representative's testimony is not binding</p> <p>5 on your client? I guess you can kind of</p> <p>6 float that one when we get to court.</p> <p>7 MR. BERNARDO: I want to take</p> <p>8 the position that it's inappropriate to</p> <p>9 ask a legal conclusion about binding form</p> <p>10 of testimony.</p> <p>11 MR. SLATER: Okay. You made</p> <p>12 your objection. You got your objection.</p> <p>13 BY MR. SLATER:</p> <p>14 Q. Doctor, were you aware -- rephrase.</p> <p>15 Did anybody ever inform you that Min</p> <p>16 Li testified for ZHP as a representative and his</p> <p>17 testimony was binding on ZHP when you were making</p> <p>18 choices as to which version of what the e-mail</p> <p>19 said you should rely on?</p> <p>20 I just want to know if you knew</p> <p>21 that.</p> <p>22 MR. BERNARDO: Object to the</p> <p>23 form of the question. Vague. Calls for</p> <p>24 legal conclusion.</p>
<p style="text-align: right;">Page 339</p> <p>1 form of the question. Legal conclusion.</p> <p>2 And still vague as to the reference to</p> <p>3 the testimony.</p> <p>4 THE WITNESS: Well, I can only</p> <p>5 say when I -- when I --</p> <p>6 BY MR. SLATER:</p> <p>7 Q. I just want to know if you knew that</p> <p>8 Dr. Li's testimony was binding on ZHP. All of his</p> <p>9 testimony -- because he testified as a corporate</p> <p>10 representative -- that it was binding, and he was</p> <p>11 speaking for the company.</p> <p>12 Did you know that?</p> <p>13 MR. BERNARDO: Object to the</p> <p>14 form of the question. It's a legal</p> <p>15 conclusion. Dr. Xue is, as we know, not</p> <p>16 a lawyer and --</p> <p>17 MR. SLATER: I'm asking if</p> <p>18 anyone told him that. I didn't ask if he</p> <p>19 agrees. So I'm not sure what the</p> <p>20 objection is.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. Can you answer, Doctor? Did anyone</p> <p>23 ever tell you that?</p> <p>24 MR. BERNARDO: You concluded</p>	<p style="text-align: right;">Page 341</p> <p>1 BY MR. SLATER:</p> <p>2 Q. It's a yes or no. Did anyone tell</p> <p>3 you that?</p> <p>4 A. I -- I don't remember anybody told</p> <p>5 me that.</p> <p>6 Q. Okay.</p> <p>7 A. But I...</p> <p>8 Q. Did anybody ever give you the typed</p> <p>9 transcription in English that ZHP presented to the</p> <p>10 court as their official transcription of the</p> <p>11 e-mail?</p> <p>12 MR. BERNARDO: Object to the</p> <p>13 form.</p> <p>14 BY MR. SLATER:</p> <p>15 Q. Translation I should say.</p> <p>16 MR. BERNARDO: Object.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. Let me ask it again.</p> <p>19 Did anybody ever give you the</p> <p>20 translation that ZHP produced to the court as a</p> <p>21 true and accurate copy of an English language</p> <p>22 translation of the July 27, 2017 e-mail, which ZHP</p> <p>23 presented to the court? Did you ever get that</p> <p>24 translation?</p>

<p style="text-align: right;">Page 342</p> <p>1 MR. BERNARDO: Object to the 2 form of the question and the 3 characterization of it. Document. 4 Assumes facts. 5 THE WITNESS: Well, as I said 6 just now, right? This I -- I read. 7 Honestly, I never ask what translate 8 those are, but I was -- I read two 9 translate along with original Chinese. 10 I told you just now. I was 11 confused for many points. The translate 12 help a little bit but not really much. 13 So I solely -- as I said, I 14 solely just rely on my expertise of the 15 organic chemistry, which I'm here for, 16 right? 17 So I understand what the 18 author of the e-mail was trying to do 19 through -- throughout his own, the full 20 -- the full document and along with the 21 attachment was what was put in there. 22 So to answer your question, I 23 don't know exactly which one you talk 24 about. Which one. Trying to say what, I</p>	<p style="text-align: right;">Page 344</p> <p>1 Lin" then there's a Bates number "is attached to 2 this Declaration as Exhibit K." 3 MR. BERNARDO: Object to the 4 form of the question. Object to asking 5 this witness about a legal document. 6 MR. SLATER: I'm literally 7 just showing him where it came from, 8 Rich. 9 MR. BERNARDO: May I finish my 10 objection and you can ask whatever you 11 want. 12 Object on the grounds of 13 foundation. 14 Go ahead, Doctor. 15 MR. SLATER: You're objecting 16 on the grounds of foundation? What's 17 that? Tell me that one so I understand 18 how to ask a better foundation question 19 when I literally just showed him the 20 declaration and the paragraph identifying 21 the exhibit. Tell me what the issue with 22 foundation is so I can fix my question. 23 MR. BERNARDO: Whether this 24 witness has even seen this document.</p>
<p style="text-align: right;">Page 343</p> <p>1 don't know that. 2 Are you -- are you adding a 3 new file to my folder? 4 (Audio malfunction). 5 (Document marked for 6 identification as Xue Exhibit 15.) 7 MR. SLATER: All right. I 8 think I just said a whole bunch of stuff 9 and no one heard it. 10 MR. BERNARDO: That is 11 correct. If you said anything, nobody 12 heard it. 13 MR. SLATER: Which is probably 14 ideal. 15 Chris, can you go back to the 16 certification? To the paragraph K, or 17 paragraph whatever that was, 13. 18 BY MR. SLATER: 19 Q. All right. Looking at paragraph 13 20 of Seth Goldberg's declaration, which is dated 21 May 14, 2021, you see paragraph 13 which says: 22 "A true and correct copy of an 23 English language translation of an e-mail dated 24 July 27, 2017, authored by ZHP employee Jinsheng</p>	<p style="text-align: right;">Page 345</p> <p>1 MR. SLATER: That's not a 2 legitimate -- 3 MR. BERNARDO: Or whether he 4 knows what it is. 5 MR. SLATER: That's not a 6 legitimate objection. 7 MR. BERNARDO: I disagree. 8 Go ahead. 9 MR. SLATER: Okay. Whether 10 he's seen it is a foundation objection? 11 Haven't even asked him that. 12 All right. I'm going to move 13 along. I'm confident in this question. 14 BY MR. SLATER: 15 Q. So now I'm going to show you Exhibit 16 K, okay, Dr. Xue? Exhibit K -- let's go to the 17 document -- is right there on the screen. And at 18 the top it says: 19 "Bulletin on the preliminary 20 findings about produced unknown impurities in 21 quenching sodium azide for the crude irbesartan." 22 Do you see that? 23 A. Can you make this -- make this 24 bigger?</p>

<p style="text-align: right;">Page 346</p> <p>1 Yeah, I -- as I said, I read.</p> <p>2 Q. It's right there on the screen.</p> <p>3 A. Yeah.</p> <p>4 Q. Do you see? Do you see the e-mail?</p> <p>5 A. I read -- this is translate, not</p> <p>6 original e-mail, right? So I saw --</p> <p>7 Q. Have you seen this translation?</p> <p>8 That's -- let me start with a new</p> <p>9 question.</p> <p>10 Have you seen this translation?</p> <p>11 A. It's really hard for me to answer</p> <p>12 this question because I, you know, I read so many</p> <p>13 things, and this for this particular document, I</p> <p>14 know for sure I read more than one English</p> <p>15 translate. I have to kind of read through to see</p> <p>16 whether I saw this.</p> <p>17 Q. Doctor, fine. You're not sure if</p> <p>18 this is the translation you saw.</p> <p>19 Let's go to page 2, and at the top</p> <p>20 of page 2, it says:</p> <p>21 "Through the secondary mass</p> <p>22 spectrometry analysis, it can be inferred that the</p> <p>23 additional NO substituent is in the cyclic</p> <p>24 compound fragment part, and it is probably that it</p>	<p style="text-align: right;">Page 348</p> <p>1 Do you see what I just read?</p> <p>2 Do you see what I just read?</p> <p>3 A. (Reviews document.)</p> <p>4 Q. Doctor, are you there?</p> <p>5 A. That's the first paragraph still,</p> <p>6 right?</p> <p>7 Q. Yeah, it's the first paragraph.</p> <p>8 A. Yes, it is what you just read, but</p> <p>9 this is one --</p> <p>10 Q. Doctor, that's what I asked you.</p> <p>11 Do you see what I just read?</p> <p>12 A. Yes.</p> <p>13 Q. So in this translation provided by</p> <p>14 ZHP, in part Dr. Lin pointed out that there is an</p> <p>15 N-nitrosodimethylamine group produced by the</p> <p>16 quenching of valsartan with sodium nitrite.</p> <p>17 That's what it says on the paper,</p> <p>18 correct?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question.</p> <p>21 BY MR. SLATER:</p> <p>22 Q. That's what the words on the page</p> <p>23 say, correct?</p> <p>24 A. I -- I --</p>
<p style="text-align: right;">Page 347</p> <p>1 is the N-NO compound."</p> <p>2 I want to stop there.</p> <p>3 You see what I just read, that first</p> <p>4 part of the sentence at the top of the page?</p> <p>5 A. I -- I saw what you read.</p> <p>6 Q. Okay. So you can see they refer to</p> <p>7 the fact that they used mass spectrometry, right?</p> <p>8 MR. BERNARDO: Object to the</p> <p>9 form of the question. Vague.</p> <p>10 BY MR. SLATER:</p> <p>11 Q. I'll ask the question again.</p> <p>12 You see that Dr. Lin who wrote the</p> <p>13 e-mail refers to a mass spectrometry analysis?</p> <p>14 You see that, right?</p> <p>15 A. I saw, yes.</p> <p>16 Q. Now, going back to where I left off.</p> <p>17 After it talks about what they were seeing in the</p> <p>18 irbesartan that they were working on, it says:</p> <p>19 "Similar to the</p> <p>20 N-nitrosodimethylamine group produced by the</p> <p>21 quenching of valsartan with sodium nitrite, its</p> <p>22 structure is very toxic, and its possible</p> <p>23 production pathways are as follows."</p> <p>24 Okay. I want to stop there.</p>	<p style="text-align: right;">Page 349</p> <p>1 Q. Is that what the words on the page</p> <p>2 say?</p> <p>3 A. Honestly, I don't think.</p> <p>4 Q. You don't think.</p> <p>5 Is that what words on the page say,</p> <p>6 Doctor?</p> <p>7 A. But this is not my approach. I'm</p> <p>8 here to offer --</p> <p>9 Q. Doctor, I'm not asking your</p> <p>10 approach. I'm taking -- I'm taking this</p> <p>11 deposition. You filibustered me for like half the</p> <p>12 deposition.</p> <p>13 MR. BERNARDO: Okay. Let's --</p> <p>14 BY MR. SLATER:</p> <p>15 Q. I'm not really that bitter about it</p> <p>16 because it's Friday so we're all happy people, but</p> <p>17 I asked you a very simple question.</p> <p>18 Do you see the words on the page</p> <p>19 showed what I just showed you?</p> <p>20 MR. BERNARDO: Object to the</p> <p>21 form of the question. Object to the</p> <p>22 argumentative nature of the question.</p> <p>23 Dr. Xue, he's just asking you</p> <p>24 to agree or disagree that he read that</p>

<p style="text-align: right;">Page 350</p> <p>1 properly from what's on the page.</p> <p>2 THE WITNESS: Sorry, Rich.</p> <p>3 Can you repeat what you said? Because</p> <p>4 you were just -- I didn't hear any</p> <p>5 basically.</p> <p>6 MR. BERNARDO: Dr. Xue, he's</p> <p>7 just asking you if you agree that he read</p> <p>8 what's on the page correctly.</p> <p>9 THE WITNESS: Oh, by reading,</p> <p>10 yes, I don't have any problem with the</p> <p>11 reading part.</p> <p>12 BY MR. SLATER:</p> <p>13 Q. So in this e-mail, according to the</p> <p>14 translation from ZHP, Dr. Lin pointed out that</p> <p>15 there's NDMA in valsartan and it's produced by the</p> <p>16 quenching of valsartan with sodium nitrite.</p> <p>17 That's what that phrase says,</p> <p>18 correct?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question. Assumes facts.</p> <p>21 Go ahead, Dr. Xue.</p> <p>22 BY MR. SLATER:</p> <p>23 Q. That's what it says, right?</p> <p>24 A. That's -- that's one form of the</p>	<p style="text-align: right;">Page 352</p> <p>1 I mean, I -- I speak Chinese, right?</p> <p>2 So it's Chinese sometimes -- how to say this?</p> <p>3 It's not -- it's not like you can word to word</p> <p>4 translate things and say, oh, this must be</p> <p>5 accurate, right?</p> <p>6 I didn't ask, but I assume</p> <p>7 everything provided to me, they are not just</p> <p>8 random translate. They are -- they are -- they</p> <p>9 must be some, you know, certified translate and</p> <p>10 then provide that to me, right?</p> <p>11 So everybody's translate has some</p> <p>12 value there. I can't answer this particular one</p> <p>13 at all. I'm not saying that or any other ones I</p> <p>14 saw.</p> <p>15 So what I really, my portion, I</p> <p>16 mention that, right? I went to the science. They</p> <p>17 talk about irbesartan, right? That clearly show</p> <p>18 in their theme, they talk about reaction happened</p> <p>19 on irbesartan. And then, too, as example to show</p> <p>20 this might be a common, common, possible common</p> <p>21 reaction.</p> <p>22 He also in his attachment showed</p> <p>23 this particular reaction also happen on the drug</p> <p>24 molecule. In this case, it's a deoscillated</p>
<p style="text-align: right;">Page 351</p> <p>1 translation, right? So if you look at other</p> <p>2 translation, they are different forms. And plus,</p> <p>3 even if just this -- this form of translation,</p> <p>4 right, that -- that N-nitrosodimethylamine group</p> <p>5 is not talk about NDMA. It talk about a group</p> <p>6 that is similar to NDMA.</p> <p>7 So what I really trying to say is,</p> <p>8 you know, if you put up one thing and to say</p> <p>9 whether this is read correct or this or that, I</p> <p>10 don't think that's a complete understanding of</p> <p>11 what the e-mail is.</p> <p>12 And point out. When I read this, I</p> <p>13 first read in Chinese. I found there are puzzles</p> <p>14 I cannot read and understand, and then I went</p> <p>15 through the science.</p> <p>16 I went through all the translate</p> <p>17 that provide to me, too. That explains some, but</p> <p>18 really not help me to -- to grab the whole</p> <p>19 information.</p> <p>20 I mean, I'm here as an organic</p> <p>21 chemist, right, trying to offer my opinion with a</p> <p>22 neutral way, but I don't think it's right that</p> <p>23 when you have multiple of these translate, you</p> <p>24 point one to say, is this word correct or not?</p>	<p style="text-align: right;">Page 353</p> <p>1 irbesartan -- sorry -- valsartan.</p> <p>2 The common theme as I show in -- see</p> <p>3 there in my report carefully I say, okay, so this</p> <p>4 is what he actually really mean to show. There's</p> <p>5 a reaction definite on this reactive nitrogen on</p> <p>6 this particular drug, irbesartan, and also this</p> <p>7 can be a general or a common theme when you have a</p> <p>8 similar reactive, a group of nitrogen atom on</p> <p>9 deoscillated valsartan and that can be actually</p> <p>10 parallel.</p> <p>11 He -- I honestly I have no clue how</p> <p>12 he actually hypothesized these things are highly</p> <p>13 toxic. That's where -- where my puzzle come from.</p> <p>14 I don't know. I mean, I respect everybody, but</p> <p>15 this person, this Dr. Jinsheng Li, I don't see he</p> <p>16 show any evidence to me showing either one of</p> <p>17 these compound are highly toxic.</p> <p>18 Because, you know, you cannot assume</p> <p>19 nitroso-compound are highly toxic. He put in</p> <p>20 there. That confuse me a lot.</p> <p>21 But I can only say my point or my</p> <p>22 conclusion or my opinion is, he's talked about</p> <p>23 irrelevant reaction, and that reaction can be a</p> <p>24 common theme as he warn his boss or, you know.</p>

<p style="text-align: right;">Page 354</p> <p>1 Yeah. So in the e-mail say, okay, 2 look, there might be something we pay attention. 3 That's all I learn from -- from -- from the whole 4 thing. 5 I really don't want to get involved 6 in this, like, look at this particular one 7 translate, tell me if this is correct. 8 Yes, I'm Chinese. 9 Q. Doctor, are you just going to talk 10 until my time is up? I mean, is that what you're 11 trying to do? 12 A. I'm trying to help. I really 13 offered -- 14 Q. You're not helping. You're not 15 helping. You're not -- you're not anywhere close 16 to helping. With all due respect, I don't know 17 what you're doing. 18 You're talking about -- you're like 19 off in all different places. I don't even know 20 what you're talking about. I'm just being really 21 honest. I don't know what you're doing. 22 A. Well, I -- 23 MR. BERNARDO: Dr. Xue. 24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 356</p> <p>1 That's a true statement with regard 2 to the zinc chloride process, right? 3 MR. BERNARDO: Object to the 4 form of the question. Assumes facts. 5 BY MR. SLATER: 6 Q. It's a true statement, right? 7 You already told me that's -- 8 that's -- that's how it was caused. That's the 9 point when the NDMA was created during the 10 quenching, right? 11 A. No, I didn't. 12 Q. Yes or no. 13 A. I didn't. 14 Q. Hold on. Stop. Stop. You 15 disagree. 16 So now your opinion is that the NDMA 17 in the zinc chloride process didn't form during 18 the quenching process. 19 Is that now -- you're now -- you 20 don't agree with that? Yes or no. 21 A. Sorry. I'm laughing. 22 Q. There's no more speeches, Doctor. 23 The speech part of the day is over. So you're 24 going to give direct answers, please.</p>
<p style="text-align: right;">Page 355</p> <p>1 Q. I don't even know what you're 2 talking about anymore, Doctor. I'm totally 3 baffled. You've baffled me. 4 MR. BERNARDO: It's late on a 5 Friday afternoon. Let's just, Dr. Xue -- 6 MR. SLATER: I'm laughing. I 7 mean, I'm actually smiling. I'm not 8 yelling at him. 9 MR. BERNARDO: I know. Adam, 10 I'm not accusing you of yelling. 11 MR. SLATER: I think I'm being 12 a pretty good sport under the 13 circumstances. 14 MR. BERNARDO: Dr. Xue, just 15 please listen to Mr. Slater's questions 16 and try and answer them as best you can. 17 I know it's late. I know you're not 18 feeling well. 19 Adam. 20 BY MR. SLATER: 21 Q. Okay. Dr. Xue, it was a true 22 statement when Dr. Lin said it that 23 N-nitrosodimethylamine was produced by the 24 quenching of valsartan with sodium nitrite.</p>	<p style="text-align: right;">Page 357</p> <p>1 A. All right. 2 Q. It's a very simple question. 3 Do you agree or disagree that the 4 NDMA formed in the zinc chloride process during 5 the sodium nitrite quenching step? 6 A. After 2018 when the whole thing 7 start to show, everybody including myself learned 8 NDMA can form during this process. 9 Q. Thank you. 10 A. I never talk about this. 11 Q. So -- 12 A. But now we look at the e-mail was 13 prior to that. 14 Q. Doctor, you got to -- 15 MR. SLATER: Rich, I'm not 16 going to let him do this. 17 MR. BERNARDO: Dr. Xue. 18 Dr. Xue. 19 MR. SLATER: I'm not going to 20 let him do this anymore. 21 MR. BERNARDO: Okay. Adam, 22 can we just take a brief break and I'll 23 see if I can -- 24 MR. SLATER: I mean, I'd</p>

<p style="text-align: right;">Page 358</p> <p>1 rather not do it in the middle of going 2 through this e-mail segment. 3 MR. BERNARDO: Yeah, I know. 4 Further -- 5 MR. SLATER: I really wanted 6 to. You could tell him on the record to 7 stop giving speeches and just answer my 8 questions. 9 MR. BERNARDO: I'm not going 10 to say. 11 Dr. Xue, I know it's late. 12 Just please listen to Mr. Slater's 13 questions. If there's more to add, I'm 14 permitted to ask you after Mr. Slater is 15 done and you can add it then. 16 So, please, just answer 17 Mr. Slater's questions. I know this is 18 confusing with the translations and it's 19 late. 20 BY MR. SLATER: 21 Q. All right. Let's be very clear. 22 In the zinc chloride process -- 23 A. Right. 24 Q. -- do you agree that the NDMA formed</p>	<p style="text-align: right;">Page 360</p> <p>1 translate, word by word translate to say 2 this is about NDMA, right? 3 So I remember clearly there's 4 one translate. They have a different 5 translate there as well. 6 BY MR. SLATER: 7 Q. How many translations did you see? 8 A. Well, I honestly don't remember. I 9 think two. 10 Q. Was this one? 11 A. I don't know it's one of the two. I 12 -- I don't remember. 13 Q. Okay. Now, let's scroll down to the 14 bottom half. Underneath the little diagrams, the 15 second paragraph. It says in the second sentence 16 of the second paragraph down there: 17 "This is a common problem in the 18 production and synthesis of sartan API." 19 Do you see that? 20 MR. BERNARDO: Object to the 21 form of the question. Same objection 22 with respect to the use of this document. 23 BY MR. SLATER: 24 Q. Do you see the sentence I just read?</p>
<p style="text-align: right;">Page 359</p> <p>1 when the quenching occurred with the sodium 2 nitrite? Is that when the NDMA formed? 3 A. Now, yes, everybody learn. 4 Q. Okay. In July of 2017, that's what 5 Dr. Lin said in this e-mail -- it's right there in 6 front of you -- that the NDMA produced by the 7 quenching of valsartan with sodium nitrite. He 8 said that in 2017. 9 You see that right in front of you, 10 correct? 11 MR. BERNARDO: Object to the 12 form of the question. Assumes facts. 13 Asked and answered. Mischaracterizes his 14 prior testimony about that sentence. 15 THE WITNESS: I disagree. 16 Because as I said, you know, this is one 17 form of the translate. And even the 18 original Chinese when I read, I was 19 confused. 20 I -- I read more than this. I 21 don't know. This might be one of the two 22 that I read. This might be the third one 23 that I read. I -- I cannot remember 24 exactly, but I cannot just look at one</p>	<p style="text-align: right;">Page 361</p> <p>1 A. By reading, yes. 2 Q. So according to this e-mail as 3 translated by ZHP, Dr. Lin advised in the e-mail 4 that this problem with the creation of 5 N-nitrosodimethylamine group due to quenching of 6 Valsartan with sodium nitrite is a common problem 7 in the production and synthesis of sartan API, 8 correct? 9 MR. BERNARDO: Object to the 10 form of the question. 11 BY MR. SLATER: 12 Q. That's what the e-mail says, right? 13 MR. BERNARDO: Object to the 14 form of the question. The 15 characterization of the document. It 16 assumes facts. 17 Go ahead, Dr. Xue. 18 THE WITNESS: I disagree as 19 I -- 20 BY MR. SLATER: 21 Q. Fine. You disagree. 22 Based on your interpretation, right? 23 A. Based on my understanding of the 24 whole article -- the whole e-mail with the</p>

<p style="text-align: right;">Page 362</p> <p>1 attachment.</p> <p>2 Q. Which includes your own</p> <p>3 interpretation and translation of the e-mail based</p> <p>4 on your reading of the Chinese language, right?</p> <p>5 A. Based on my reading of everything,</p> <p>6 not just the Chinese. Also every translate that</p> <p>7 provide to me. Also the reference that attached</p> <p>8 to this e-mail as well. That's -- that's how I</p> <p>9 define myself.</p> <p>10 Q. Okay. He then says:</p> <p>11 "It is recommended to improve to</p> <p>12 other quenching method, such as NaClO, in addition</p> <p>13 to optimize the quenching process for sodium azide</p> <p>14 in valsartan."</p> <p>15 So he's literally pointing out we</p> <p>16 need to optimize the quenching because he's</p> <p>17 pointed out that the quenching of the sartans is</p> <p>18 causing nitrosamines to form.</p> <p>19 That was a good suggestion, right?</p> <p>20 Let's optimize the quenching so we don't create</p> <p>21 nitrosamines. That was a smart suggestion,</p> <p>22 correct?</p> <p>23 MR. BERNARDO: Object to the</p> <p>24 form of the question, to the use of this</p>	<p style="text-align: right;">Page 364</p> <p>1 is what he offered to do. I think to me</p> <p>2 it's definitely some option you can</p> <p>3 actually consider to do that that's --</p> <p>4 that's one of them.</p> <p>5 But the two reaction they talk</p> <p>6 about is actually these two I mention.</p> <p>7 Sorry I confuse you first place, but</p> <p>8 it's --</p> <p>9 BY MR. SLATER:</p> <p>10 Q. It's not confusing me, Doctor.</p> <p>11 You're just eating all my time up.</p> <p>12 A. But these are the two reactions he</p> <p>13 talk about, and so he -- he suspect these two</p> <p>14 compound, nitroso-compounds, they can be highly</p> <p>15 toxic, which I don't agree. I don't know where he</p> <p>16 gets supported from.</p> <p>17 But I think as an employee seeing</p> <p>18 nitroso-compound like these two and warn his boss</p> <p>19 about this as a potential and then suggest some</p> <p>20 potential solution for this, I feel this --</p> <p>21 this -- this is logic.</p> <p>22 Q. If we go down to the last paragraph,</p> <p>23 he talks about the patent?</p> <p>24 A. Right.</p>
<p style="text-align: right;">Page 363</p> <p>1 document, to the translation, and to the</p> <p>2 characterization of his prior testimony.</p> <p>3 Go on.</p> <p>4 THE WITNESS: Well, something</p> <p>5 Dr. Jinsheng Lin is talking here. I</p> <p>6 never against that. I think that's my</p> <p>7 understanding as well.</p> <p>8 However, the reaction he refer</p> <p>9 to here, also clearly to me after I read</p> <p>10 the whole thing and I see the whole</p> <p>11 situation is the reaction to form what he</p> <p>12 join up there, the nitroso-compound.</p> <p>13 Also, the deoscillated</p> <p>14 valsartan in that patent also can form a</p> <p>15 nitroso-compound. These two compounds he</p> <p>16 hypothesized can be, and he then offered</p> <p>17 a potential optimization. Say, hey, if</p> <p>18 we not using the quenching, using other</p> <p>19 quenching as people already reported in</p> <p>20 their patent, we might be able to get</p> <p>21 around these potential -- potential</p> <p>22 nitroso-compound that he raised.</p> <p>23 I think that I agree with you.</p> <p>24 To look for a different quenching process</p>	<p style="text-align: right;">Page 365</p> <p>1 Q. He talks about the fact that they</p> <p>2 proposed that the use of NaNO₂ -- that's sodium</p> <p>3 nitrite, right?</p> <p>4 A. Correct.</p> <p>5 Q. That sodium nitrite quenching will</p> <p>6 produce N-NO impurities. And then he says:</p> <p>7 "In the meanwhile, our Huahai crude</p> <p>8 valsartan was detected by LC-MS."</p> <p>9 Do you see that?</p> <p>10 A. Correct.</p> <p>11 Q. So he's pointing out that the</p> <p>12 nitroso-compound that they detected in their</p> <p>13 valsartan, they detected it with LC-MS.</p> <p>14 That's what he's saying, correct?</p> <p>15 A. What they were saying is the</p> <p>16 deoscillated valsartan. As I show you in my</p> <p>17 report, right? That compound can be nitrosamine.</p> <p>18 So that's the compound they talk.</p> <p>19 I just want to make -- make it clear</p> <p>20 what we talk about here. They not talk about</p> <p>21 valsartan the drug itself get nitrosylate. To my</p> <p>22 knowledge today they ask me there still be no</p> <p>23 chance that you can do nitrosylation on valsartan</p> <p>24 drug itself. That's my -- my -- my honest</p>

<p style="text-align: right;">Page 366</p> <p>1 feeling.</p> <p>2 What the patent does and what the</p> <p>3 patent show us is this compound deoscillated</p> <p>4 valsartan can actually get nitrosylation reaction</p> <p>5 to give you this. I believe they call it impurity</p> <p>6 K maybe, right? So they -- they talk about that,</p> <p>7 right?</p> <p>8 So it's not talk about valsartan at</p> <p>9 all or anything about even. This -- this whole</p> <p>10 art -- this whole document has nothing to do with</p> <p>11 NDMA or NDEA.</p> <p>12 Q. Well, where he says -- let's go back</p> <p>13 up to the top of the document. Then we'll move to</p> <p>14 something else.</p> <p>15 Where he says that what he was</p> <p>16 seeing in the irbesartan was similar to the NDMA</p> <p>17 produced by the quenching of valsartan with sodium</p> <p>18 nitrite, that's relevant to this case, right?</p> <p>19 MR. BERNARDO: Object to the</p> <p>20 form of the question and the</p> <p>21 characteration -- characterization of the</p> <p>22 documents being used.</p> <p>23 Go on.</p> <p>24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 368</p> <p>1 A. No. No. I have to -- I have to be</p> <p>2 clear.</p> <p>3 Q. No. No, Doctor, we're not. You</p> <p>4 don't get -- you don't get to run the deposition.</p> <p>5 That's what it says. It says quenching of</p> <p>6 valsartan.</p> <p>7 MR. BERNARDO: He's trying to</p> <p>8 explain why he disagrees.</p> <p>9 MR. SLATER: This is -- he</p> <p>10 disagrees that the word says "valsartan"?</p> <p>11 MR. BERNARDO: Let him finish</p> <p>12 his answer and he'll explain what he</p> <p>13 means.</p> <p>14 MR. SLATER: You know what? I</p> <p>15 withdraw the question. So we're not</p> <p>16 going to hear the speech.</p> <p>17 BY MR. SLATER:</p> <p>18 Q. If I'm correct that Jinsheng Lin</p> <p>19 said in this e-mail that there was NDMA in</p> <p>20 valsartan and it was formed by sodium nitrite</p> <p>21 quenching, and that was known in July of 2017,</p> <p>22 does that impact any of your opinions?</p> <p>23 If that's the case, does that impact</p> <p>24 any of your opinions in this case?</p>
<p style="text-align: right;">Page 367</p> <p>1 Q. That's present -- that's relevant to</p> <p>2 the case, right?</p> <p>3 What was happening with valsartan</p> <p>4 and how the NDMA was formed, that's relevant,</p> <p>5 right?</p> <p>6 MR. BERNARDO: Same</p> <p>7 objections.</p> <p>8 THE WITNESS: Even if -- even</p> <p>9 if we only look at this translate, right,</p> <p>10 not consider any other things. First of</p> <p>11 all, I think that's biased already.</p> <p>12 Even if this, they clearly</p> <p>13 talk about the compound happen during the</p> <p>14 valsartan process where the deoscillated</p> <p>15 valsartan can actually react to form a</p> <p>16 nitroso-compound. These are --</p> <p>17 BY MR. SLATER:</p> <p>18 Q. I'm sorry, Doctor.</p> <p>19 Where does he say -- where does he</p> <p>20 say valsartan -- deoscillated valsartan?</p> <p>21 It says "quenching of valsartan with</p> <p>22 sodium nitrite."</p> <p>23 That's what it says in those words,</p> <p>24 right?</p>	<p style="text-align: right;">Page 369</p> <p>1 MR. BERNARDO: Object to form.</p> <p>2 BY MR. SLATER:</p> <p>3 Q. Yes or no. It's a simple yes-or-no</p> <p>4 question.</p> <p>5 MR. BERNARDO: Object to the</p> <p>6 form of the question. It calls for</p> <p>7 speculation. Assumes facts.</p> <p>8 Go on.</p> <p>9 THE WITNESS: Well, you said a</p> <p>10 lot of assumptions, right? Let me -- let</p> <p>11 me walk through this.</p> <p>12 You said if I -- if I -- if I</p> <p>13 just --</p> <p>14 BY MR. SLATER:</p> <p>15 Q. You don't understand the question.</p> <p>16 I'll ask it again. I didn't have a lot of</p> <p>17 assumptions. Let me ask it again.</p> <p>18 Well, let me ask you this.</p> <p>19 In July of 2017, there was NDMA in</p> <p>20 the valsartan manufactured with the zinc chloride</p> <p>21 process, and as we talked about before, the NDMA</p> <p>22 formed during the sodium nitrite quenching, right?</p> <p>23 A. So after all these analysis, yes, we</p> <p>24 now know that at that time or even earlier it was</p>

<p style="text-align: right;">Page 370</p> <p>1 formed. But nobody knows till 2018, right.</p> <p>2 Q. Well, if I'm correct -- well,</p> <p>3 rephrase.</p> <p>4 If Min Li is correct in how he</p> <p>5 translated the document when he read it under oath</p> <p>6 for ZHP that the e-mail said that what they were</p> <p>7 seeing in the irbesartan was similar to the NDMA</p> <p>8 in valsartan which was created by the sodium</p> <p>9 nitrite quenching, if that is what the e-mail</p> <p>10 said, then people within ZHP knew about the issue</p> <p>11 with the NDMA in July of 2017, correct?</p> <p>12 MR. BERNARDO: Object to the</p> <p>13 form of the question. Vague. Object to</p> <p>14 the characterization of Min Li's</p> <p>15 testimony. Assumes facts.</p> <p>16 Go ahead, Dr. Xue.</p> <p>17 THE WITNESS: Well, I think I</p> <p>18 read Min Li's depositions. I read -- I</p> <p>19 don't remember exactly what he said.</p> <p>20 I don't think your</p> <p>21 characterization saying he agreed with</p> <p>22 everything that you just said. I don't</p> <p>23 remember it clearly get that sense. I</p> <p>24 remember he somehow -- I don't know</p>	<p style="text-align: right;">Page 372</p> <p>1 Q. If ZHP knew -- rephrase.</p> <p>2 If Jinsheng Lin -- well, rephrase.</p> <p>3 I'll ask it straight-out.</p> <p>4 If the e-mail says that -- I'll ask</p> <p>5 it even differently.</p> <p>6 If ZHP knew that there was NDMA in</p> <p>7 the valsartan as of July 2017 and never disclosed</p> <p>8 it, that would be inexcusable, right?</p> <p>9 MR. BERNARDO: Object to the</p> <p>10 form of the question. Argumentative.</p> <p>11 Listen to his question,</p> <p>12 Dr. Xue.</p> <p>13 THE WITNESS: So you're</p> <p>14 asking if -- if -- if ZHP knew NDMA</p> <p>15 present prior to this e-mail? Was that</p> <p>16 your question? Then they will be</p> <p>17 inexcusable? That was -- that was what</p> <p>18 you asking?</p> <p>19 BY MR. SLATER:</p> <p>20 Q. If ZHP knew there was NDMA in the</p> <p>21 valsartan in July of 2017 or earlier and didn't</p> <p>22 tell anybody, that would be inexcusable, right?</p> <p>23 A. If that's the case, yes.</p> <p>24 Q. And you're just trying to come to an</p>
<p style="text-align: right;">Page 371</p> <p>1 what -- what -- what translate or whether</p> <p>2 the -- what you are showing or discuss</p> <p>3 with him about any form.</p> <p>4 I don't remember that, but I</p> <p>5 remember he was pretty like -- I don't</p> <p>6 know -- surprised or something. I don't</p> <p>7 know whether he get a chance to read this</p> <p>8 before.</p> <p>9 I just have many questions.</p> <p>10 Like whether he actually considered. I</p> <p>11 mean, you actually showed him the -- the</p> <p>12 attachment. All these I don't know. I</p> <p>13 don't want to speculate.</p> <p>14 As I said, I'm here. I'm an</p> <p>15 expert.</p> <p>16 BY MR. SLATER:</p> <p>17 Q. All right.</p> <p>18 A. I just want to tell the truth on</p> <p>19 what I actually went in to see all these documents</p> <p>20 provide to me. I honestly judge based on my</p> <p>21 understanding of the science. I try to explain to</p> <p>22 you. Although you say I confuse you, but I really</p> <p>23 try my best, right? I wrote that in my report as</p> <p>24 well. Yeah.</p>	<p style="text-align: right;">Page 373</p> <p>1 understanding of what they knew based on your</p> <p>2 reading of multiple translations and your own</p> <p>3 interpretation of the Chinese version of the</p> <p>4 e-mail and whatever else you saw.</p> <p>5 You don't actually have an opinion</p> <p>6 as to what the e-mail really said because you're</p> <p>7 looking at so many different sources of</p> <p>8 translation, right?</p> <p>9 MR. BERNARDO: Object to the</p> <p>10 form of the question. Object to the</p> <p>11 characterization of his prior testimony.</p> <p>12 THE WITNESS: I disagree. I</p> <p>13 think I clearly offered my opinion on</p> <p>14 this one.</p> <p>15 BY MR. SLATER:</p> <p>16 Q. And part of that opinion is based on</p> <p>17 your own reading of the document in Chinese,</p> <p>18 right?</p> <p>19 A. That's definitely part of it.</p> <p>20 There's other parts. All the information. I</p> <p>21 definitely consider everything that -- that came</p> <p>22 to me I asked for together to form my opinion.</p> <p>23 MR. SLATER: Let's take a</p> <p>24 break.</p>

<p style="text-align: right;">Page 374</p> <p>1 THE VIDEOGRAPHER: Time right 2 now is 5:50 p.m. We're off the record. 3 (Recess.) 4 THE VIDEOGRAPHER: Time right 5 now is 5:38 p.m. We're back on the 6 record. 7 BY MR. SLATER: 8 Q. On page 55 of your report at the 9 bottom, in talking about that July 2017 e-mail you 10 say: 11 "In addition, ZHP employees who have 12 testified about the e-mail have made clear that 13 'due to insufficient extent and depth of process 14 research at the early stage, as well as 15 insufficient study and understanding of potential 16 genotoxic impurities, only side reaction product 17 and degradation products were studied' with 18 respect to Irbesartan, and therefore ZHP 'was 19 unaware of the further reaction between 20 degradation products and raw material' related to 21 Irbesartan." 22 Do you see that? 23 A. I do. 24 Q. And you cite in note 122 to Min Li's</p>	<p style="text-align: right;">Page 376</p> <p>1 A. About why they -- they didn't pursue 2 anything on this irbesartan because it's not 3 relevant. 4 Q. Now what we're going to do is, I'm 5 going to go to the testimony you cited, which is 6 Min Li, April 22, 2021, page 528 line 14. 7 And you can see at line 14 it says: 8 "We have on the screen Exhibit 212, 9 which is a report, and the topic title is 10 'Investigation regarding an unknown impurity,' and 11 then in parentheses 'Genotoxic impurity' with 12 regard to valsartan. 13 "Do you see that?" 14 A. Do I have that document also in my 15 folder? 16 Q. I don't know what you're asking me, 17 Doctor, but I'm showing you the transcript right 18 on the screen, please. 19 A. Well, yeah, but can I see the -- the 20 -- you put everything in my -- 21 MR. SLATER: It's there. 22 What exhibit is it? 23 Exhibit 16 is the transcript. 24 (Document marked for</p>
<p style="text-align: right;">Page 375</p> <p>1 deposition transcript. 2 You see that? 3 A. (Reviews document). 4 Q. Doctor, this is your report. It 5 says 122 at the end of the sentence I read at the 6 bottom of the page? 7 A. Yeah. Sorry. Sorry. I was -- 8 Q. That's Min Li's deposition, right? 9 A. Yes. 10 Q. And after you say that in your 11 report, you say: 12 "As a result, Mr. Lin's e-mail 13 discussing Irbesartan could not have been 14 addressing the formation of nitrosamines as a 15 result of the potential degradation of DMF, which 16 is what plaintiffs' experts assert resulted in the 17 formation of nitrosamines during the zinc chloride 18 process for Valsartan API." 19 You see that? 20 A. I saw that. 21 Q. So you're relying in part on that 22 testimony from Min Li for your understanding and 23 interpretation of the e-mail, correct? That's 24 what you're saying in the report?</p>	<p style="text-align: right;">Page 377</p> <p>1 identification as Xue Exhibit 16.) 2 THE WITNESS: Can you please 3 let me know the page number as well? 4 BY MR. SLATER: 5 Q. It's page 528 line 14. 6 A. Well, it is loading on my computer. 7 So give me a second. 8 Still loading, though. 9 Q. That's all right. Take all the time 10 you want. At some point, I'm going to run out. 11 It's okay. 12 A. For some reason, this way it's just 13 loading. The circle is just going. 14 Q. Do whatever you want. Take as long 15 as you want. I mean, it's only -- I've only lost 16 hours in this -- in this deposition already. It's 17 okay. 18 A. Well, this is not me, right? So. 19 Q. I don't really understand why you 20 need to do that. I literally just showed you what 21 you cited in your report, but okay. 22 MR. BERNARDO: Object to the 23 form of the question. I don't think it's 24 inappropriate for witness to actually ask</p>

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1 to see a transcript of what you're
2 showing one page. That's the way it
3 would ordinarily be done if we were in
4 person.
5 MR. SLATER: That's okay. I
6 think I've been extraordinarily easygoing
7 under the circumstances here. I've got a
8 smile on my face. So it's okay.
9 I assume you're going to be
10 reasonable if all of a sudden we get down
11 to my seven hours so we don't have any
12 issues. But, you know, you can do
13 whatever you want.
14 THE WITNESS: For some
15 reason, this -- this document is really
16 loading like right now.
17 MR. SLATER: Shall we keep the
18 clock going while his document is
19 loading? What do you want to do, Rich,
20 just wait until the clock is out?
21 Why don't you let it spin for
22 30 more minutes. Take whatever time you
23 want.
24 MR. BERNARDO: All right.

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1 Adam, come on. Let's just chill here.
2 If you want to go off the clock, go off
3 the clock. It's your deposition. He's
4 entitled to read the document.
5 MR. SLATER: All right. So
6 let's go off the clock and he can read
7 the deposition.
8 Yeah. Let's go off the -- off
9 the clock and you probably should
10 download the transcript I'm told.
11 THE WITNESS: How can I?
12 Because I was -- I was doing everything
13 else today was -- was fine. So only this
14 one 16 when I click it, it just didn't.
15 BY MR. SLATER:
16 Q. If you go to the folder, the
17 document is there and you can download it.
18 MR. HENRY: There's -- there's
19 a G with three periods next to G. Click
20 that and go to options to download it.
21 THE WITNESS: When I click
22 the three dots, it only says the direct
23 link of this. Or I can download all
24 files it says.

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1 Oh, this one. Okay. Let me
2 try this. Okay. I'm downloading now.
3 Okay. Great. It looks like
4 it's downloading. We can go back to
5 talk.
6 MR. BERNARDO: Well, let's
7 wait until you have it, Dr. Xue.
8 THE WITNESS: Oh, okay.
9 I'm opening it.
10 BY MR. SLATER:
11 Q. It's okay.
12 A. Okay. It's up here.
13 MR. BERNARDO: Why don't you
14 get to the page that he's referring to,
15 Dr. Xue.
16 BY MR. SLATER:
17 Q. Yeah, read it. You said you want to
18 read it. It's okay.
19 I'm not on the clock, Doc. You can
20 read the whole deposition if you want. I don't
21 mind.
22 A. (Reviews document.)
23 Yeah, I think I read this page and
24 we can go back to talk because I really want to go

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1 home tonight.
2 Q. I don't care when I go home. I'll
3 work as late as we need to. I honestly don't
4 care. If I get done with you, I'm going to work
5 on other stuff all night. It doesn't matter.
6 A. Please consider I'm still
7 COVID-positive.
8 Q. So are you ready to answer questions
9 about this?
10 A. Yes. Are we back on the clock?
11 Q. Can we go back on?
12 All right. We're going.
13 Looking at the testimony you cited
14 in your report, it refers to the fact that this
15 report that you cited is the "Investigation
16 regarding an unknown impurity" and then
17 parentheses "Genotoxic impurity" with regard to
18 valsartan.
19 You see the testimony says it's a
20 report regarding valsartan, right?
21 A. Right.
22 MR. BERNARDO: Object to the
23 form of the question and the
24 characterization of his testimony.

<p style="text-align: right;">Page 382</p> <p>1 THE WITNESS: Yeah. By</p> <p>2 reading that section on line 14 to 18,</p> <p>3 that was question asked about.</p> <p>4 BY MR. SLATER:</p> <p>5 Q. You said in your report that that</p> <p>6 report that I was asking Dr. Li about had to do</p> <p>7 with irbesartan.</p> <p>8 So when you said that in your</p> <p>9 report, you were incorrect, right?</p> <p>10 MR. BERNARDO: Object to the</p> <p>11 form of the question.</p> <p>12 THE WITNESS: Well, with this</p> <p>13 short time, I really don't recall what I</p> <p>14 was reading when I write that part. I</p> <p>15 cannot say yes or no this easy. Because</p> <p>16 I think my point there was -- was fairly</p> <p>17 clear.</p> <p>18 That whole e-mail case was</p> <p>19 about irbesartan, and then they talk</p> <p>20 about why they didn't do further study</p> <p>21 because it was just a lab scale discovery</p> <p>22 or development, not even in the real</p> <p>23 factory yet. So they decide not pursue</p> <p>24 any further of that.</p>	<p style="text-align: right;">Page 384</p> <p>1 insufficient study and understanding of potential</p> <p>2 genotoxic impurities, only side reaction product</p> <p>3 and degradation products were studied' with</p> <p>4 respect to Irbesartan, and therefore ZHP 'was</p> <p>5 unaware of the further reaction between</p> <p>6 degradation products and raw material' related to</p> <p>7 Irbesartan."</p> <p>8 Then you say:</p> <p>9 "As a result, Mr. Lin's e-mail</p> <p>10 discussing Irbesartan could not have been</p> <p>11 addressing the formation of nitrosamines," etc.</p> <p>12 Okay. So you were -- you were</p> <p>13 basing your opinion in part on that testimony</p> <p>14 relating to irbesartan.</p> <p>15 That's what your report says, right?</p> <p>16 That's what the report says, Doctor,</p> <p>17 right? It says "irbesartan," correct?</p> <p>18 A. Yes, I wrote that.</p> <p>19 Q. Okay. And now let's go to the</p> <p>20 bottom of page 529 line 17, which is part of the</p> <p>21 testimony you cited for this proposition.</p> <p>22 If we look at page 529 line 17, it</p> <p>23 says -- looking at this report about valsartan</p> <p>24 under the heading of 5.2 "Control strategy," it</p>
<p style="text-align: right;">Page 383</p> <p>1 That's what I meant to -- to</p> <p>2 show there.</p> <p>3 BY MR. SLATER:</p> <p>4 Q. You said in your report when you</p> <p>5 were talking about why the e-mail means what you</p> <p>6 think it means and what you told us you think it</p> <p>7 means, that one of the reasons for that was</p> <p>8 because of that testimony from Dr. Li with regard</p> <p>9 to what you thought was a report about irbesartan.</p> <p>10 That's what you said on page 55 and</p> <p>11 56 of your report, correct?</p> <p>12 It's a yes-or-no question. That's</p> <p>13 what you said, right?</p> <p>14 A. I hope it can be a yes-or-no</p> <p>15 question but really is not.</p> <p>16 Q. Is that what you said in your</p> <p>17 report? Did you refer to this as being -- that</p> <p>18 you said witnesses test -- rephrase.</p> <p>19 You said in your report on bottom of</p> <p>20 55:</p> <p>21 "In addition, ZHP employees who have</p> <p>22 testified about the e-mail have made clear that</p> <p>23 'due to insufficient extent and depth of process</p> <p>24 research at the early stage, as well as</p>	<p style="text-align: right;">Page 385</p> <p>1 says:</p> <p>2 "'Due to insufficient extent and</p> <p>3 depth of process research at the early stage, as</p> <p>4 well as insufficient study and understanding of</p> <p>5 potential genotoxic impurities, only side reaction</p> <p>6 product and degradation products were studied, and</p> <p>7 was unaware of the further reaction between</p> <p>8 degradation products and raw material.'"</p> <p>9 Now having seen that that relates to</p> <p>10 valsartan, that's important that ZHP acknowledged</p> <p>11 in an internal document that they did an</p> <p>12 "insufficient extent and depth of process research</p> <p>13 at the early stage" and "insufficient study and</p> <p>14 understanding of potential genotoxic impurities."</p> <p>15 That's important that ZHP stated in</p> <p>16 a document that that occurred, correct? That's of</p> <p>17 importance, right?</p> <p>18 A. I disagree because --</p> <p>19 Q. Fine. You disagree. That's it.</p> <p>20 That's what I asked you. You disagree.</p> <p>21 So let me ask you.</p> <p>22 A. Can I explain, though?</p> <p>23 Q. No, you can't because I asked you do</p> <p>24 you -- is that yes or no, you said you disagree.</p>

<p style="text-align: right;">Page 386</p> <p>1 Your lawyer can ask you five hours of questions 2 after this if you want. 3 So let me go to the next step. 4 So you're saying that ZHP admitted 5 in an internal document "insufficient extent and 6 depth of process research at the early stage" and 7 admitted "insufficient study and understanding of 8 potential genotoxic impurities," that doesn't have 9 any impact on your opinions regarding the adequacy 10 of their risk assessment into the scientific 11 reactions. 12 That's your testimony, correct? 13 A. What I'm saying is this irbesartan 14 product is a totally separate project they are 15 working on. Although they both called sartans, 16 they have involve totally different process. 17 In this particular case, they are in 18 the baby stage. They are still in the lab scale 19 discovery stage. They are not talk about any API 20 process or anything yet. They only talk about in 21 lab space the possibility of producing irbesartan. 22 I said they found this potential problem. 23 Q. Dr. Xue, the whole point that I'm 24 making to you is that that statement about</p>	<p style="text-align: right;">Page 388</p> <p>1 It was reported about valsartan. 2 Are you just realizing that for the 3 first time right now? 4 I assume you are or you would have 5 changed your report, right? 6 MR. BERNARDO: Object. Object 7 to the form of the question. 8 Argumentative. Object to the 9 characterization of the document. 10 BY MR. SLATER: 11 Q. I'll restate then. 12 On that point -- 13 A. I don't think I -- 14 Q. -- Min Li's testimony at the bottom 15 of page 529, he's not talking about irbesartan. 16 He's reading from a report about valsartan. 17 You didn't realize that, did you? 18 MR. BERNARDO: Object to the 19 form of the question. The 20 characterization. 21 BY MR. SLATER: 22 Q. You're just realizing when I'm 23 telling you, right? 24 Because your report said it was</p>
<p style="text-align: right;">Page 387</p> <p>1 "insufficient extent and depth of process 2 research" and "insufficient study and 3 understanding of potential genotoxic 4 impurities" -- I don't know if you're catching 5 on -- they wrote that about valsartan, not about 6 irbesartan. 7 Do you not realize that even now 8 after I just showed you? 9 A. I disagree. 10 Q. Okay. So you think that that 11 document that you're -- that's being quoted here 12 in Min Li's testimony is about irbesartan? 13 A. Well, you showed me this -- this 14 single paragraph. You talk about genotoxic 15 impurity regard to valsartan. I -- I don't know 16 the linkage between here and what I wrote here. 17 Q. There is no linkage. That's the 18 whole point I'm trying to show you, Doctor. 19 A. Right. 20 Q. Is when you wrote in your report 21 that that testimony by Min Li had to do with 22 irbesartan, I'm pointing out to you that you were 23 wrong in your report and it actually had nothing 24 to do about irbesartan. It was about valsartan.</p>	<p style="text-align: right;">Page 389</p> <p>1 about irbesartan. I'm pointing out to you it's 2 about valsartan. 3 You didn't know before right now, 4 right? 5 MR. BERNARDO: Object to the 6 form of the question. Vague and the 7 characterization of the prior testimony. 8 THE WITNESS: I really don't 9 think it's clear to me what you are 10 talking about. I think I -- 11 BY MR. SLATER: 12 Q. All right. I'll tell you right now 13 it's not clear. 14 Look at the bottom of page 529 -- 15 it's right on the screen -- line 17 where it says: 16 "Under the heading of 5.2, 'Control 17 strategy.' 18 What I'm pointing out to you is what 19 it says right after that. They're talking about 20 valsartan. They're talking about their work with 21 valsartan, not irbesartan. 22 MR. BERNARDO: Object to the 23 form of the question. 24 BY MR. SLATER:</p>

<p style="text-align: right;">Page 390</p> <p>1 Q. I assume this is the first time 2 you're realizing that, right? 3 MR. BERNARDO: Object to the 4 form of the question. Argumentative. 5 THE WITNESS: No. I'm here to 6 answer questions that I can understand 7 what the question is. I see -- 8 BY MR. SLATER: 9 Q. Doctor, I showed you on the prior 10 page that the document was identified was a report 11 about valsartan, not irbesartan. 12 Your report is wrong. You called it 13 irbesartan. That report is not about irbesartan. 14 This language at the bottom of page 529 was 15 written by ZHP people about their assessment of 16 the process for valsartan. 17 MR. BERNARDO: Object to the 18 form of the question. 19 BY MR. SLATER: 20 Q. You didn't realize that before right 21 now, correct? 22 A. Are you trying to -- are you trying 23 to accuse me that I use the wrong word in my 24 report? Because I honestly --</p>	<p style="text-align: right;">Page 392</p> <p>1 Q. Does that matter to you? 2 A. I don't think that's my opinion. 3 Q. Is that -- 4 A. I don't think that's my opinion at 5 all. 6 Q. I'm sorry. What? 7 A. I'm sorry. I'm sorry. I didn't 8 hear you just now. 9 Q. I said: Does that matter to you in 10 drawing your opinions that now you know that ZHP 11 internally admitted "insufficient extent and depth 12 of process research at the early stage" and 13 admitted "insufficient study and understanding of 14 potential genotoxic impurities"? 15 That's a significant fact to an 16 objective expert who's actually trying to get to 17 the truth, right? 18 MR. BERNARDO: Object to the 19 form of the question. Object to the 20 characterization. Object to this line of 21 questioning and the inability of the 22 witness to be able to look at this and 23 consider what you're trying to say in 24 order to answer your question.</p>
<p style="text-align: right;">Page 391</p> <p>1 Q. No, I'm not accusing you of 2 anything. 3 What I'm pointing out to you is that 4 when you said this language was about their 5 irbesartan investigation, I'm pointing out to you 6 that you are wrong. It was actually about 7 valsartan. 8 MR. BERNARDO: Object to the 9 form of the question. 10 BY MR. SLATER: 11 Q. And what I'm asking you is: Now 12 knowing that they admitted in an internal document 13 "insufficient extent and depth of process 14 research" and "insufficient study and 15 understanding of potential genotoxic impurities," 16 that's important to you now, knowing that ZHP 17 admitted internally they didn't do an adequate 18 research and they didn't have adequate 19 understanding. 20 That matters to you as an expert, 21 right? 22 MR. BERNARDO: Object to the 23 form of the question. Characterization. 24 BY MR. SLATER:</p>	<p style="text-align: right;">Page 393</p> <p>1 Go on. 2 BY MR. SLATER: 3 Q. It's important, right? 4 A. No, I really -- I don't understand 5 this. I -- I -- my opinion was clearly state 6 through my understanding of this e-mail what this 7 about, why they didn't pursue this case afterward. 8 Q. Doctor, this testimony has nothing 9 to do with the e-mail. That's the point I'm 10 making to you. 11 This testimony by Min Li, this has 12 nothing to do with the e-mail. 13 You drew -- you drew a connection 14 between this testimony and this valsartan report 15 to irbesartan and the e-mail that nobody has ever 16 made. There is no connection. That's the point 17 I'm making to you. 18 Your report is incorrect and now 19 that you're seeing that, you need to rethink your 20 opinions, right? 21 A. No, I don't. I really don't. 22 Q. Okay. So -- 23 A. Because I don't -- I don't know you 24 show me this testimony. So what is the back --</p>

<p style="text-align: right;">Page 394</p> <p>1 why you show me this page? What you want --</p> <p>2 because there's only one --</p> <p>3 Q. Because you cited it in your report.</p> <p>4 On page 55 and 56 in reference number 122, this is</p> <p>5 the testimony you cited, Doctor. You cited it</p> <p>6 thinking that Min Li was talking about irbesartan,</p> <p>7 but he wasn't. He was talking about valsartan.</p> <p>8 He was -- there's a report admitting</p> <p>9 insufficient research.</p> <p>10 A. I might -- well, that might be my</p> <p>11 typo, might be my mistake of -- of citing. If</p> <p>12 that's what you accuse me, I, you know, I have</p> <p>13 nothing against that. Because I may just put a</p> <p>14 wrong line or I may put that to my human error. I</p> <p>15 take it, whatever responsibility that is.</p> <p>16 But I, you know, apparently I didn't</p> <p>17 intend to cite anything that is --</p> <p>18 Q. Okay.</p> <p>19 A. -- wrong.</p> <p>20 Q. So now -- so having said that, now</p> <p>21 that you know that when Min Li was testifying here</p> <p>22 he was testifying about an internal report about</p> <p>23 their valsartan research, and he admits that they</p> <p>24 did insufficient process research and they had</p>	<p style="text-align: right;">Page 396</p> <p>1 come from. I told you. I don't agree with that.</p> <p>2 Q. If I'm correct that ZHP in the</p> <p>3 internal report wrote the language that you see</p> <p>4 there starting on line 18 on page 529 of Min Li's</p> <p>5 April 22, 2021 deposition, that's important for</p> <p>6 you to consider in forming your opinions.</p> <p>7 It's something you need to at least</p> <p>8 take into account, right?</p> <p>9 A. You know, again, your question is so</p> <p>10 hypothetical, right? You almost ask me if they</p> <p>11 agree that they did something wrong, are they</p> <p>12 wrong, right? So that's --</p> <p>13 Q. No, I'm asking you if they agree</p> <p>14 that there was "inadequate extent and depth of</p> <p>15 process research at the early stage" and</p> <p>16 "insufficient study and understanding of potential</p> <p>17 genotoxic impurities," is that something you</p> <p>18 should take into account in forming your opinions</p> <p>19 about the adequacy of their risk assessment?</p> <p>20 A. Well, it's -- we talk about</p> <p>21 different things, right? So this project that we</p> <p>22 talk about when they have these comments about</p> <p>23 insufficient this or the depth of this, it's baby</p> <p>24 stage projects, right?</p>
<p style="text-align: right;">Page 395</p> <p>1 insufficient study and understanding of potential</p> <p>2 genotoxic impurities, if -- if that's true that</p> <p>3 ZHP said that about their valsartan and the work</p> <p>4 they did on valsartan, do you agree it's something</p> <p>5 you should take into account in forming your</p> <p>6 opinions?</p> <p>7 A. I totally disagree. Because if</p> <p>8 that's my human error, just put it on me and say,</p> <p>9 oh, that's what you mean. I cannot do that,</p> <p>10 right? So you cannot say because I -- I got the</p> <p>11 wrong line of citation, you say, oh, this is what</p> <p>12 you say. I mean, ZHP already know they didn't do</p> <p>13 enough of good work of risk assessment for their</p> <p>14 valsartan.</p> <p>15 So I'm -- I'm here, you know, as a</p> <p>16 scientist. I spend the whole day trying to say</p> <p>17 based on my knowledge why these three are my</p> <p>18 opinions.</p> <p>19 I told you, don't agree that, you</p> <p>20 know, from any point -- point of Min Li's</p> <p>21 deposition show that they already know they have</p> <p>22 insufficient studies. All these three already</p> <p>23 admitted.</p> <p>24 I just -- I don't know where they</p>	<p style="text-align: right;">Page 397</p> <p>1 So when you have these there in the</p> <p>2 labs and you see some obvious situations.</p> <p>3 Sometime, you know, I do the same. When my</p> <p>4 postdoc come to me and say, hey, we try your idea.</p> <p>5 You know what? After I try a couple reactions, I</p> <p>6 see something really weird happen. What we going</p> <p>7 to do? If he has another project which is</p> <p>8 important, I may just say, okay, let's -- let's</p> <p>9 shelf that for now and we can worry about that.</p> <p>10 I don't think that has any revision</p> <p>11 with a different product of the same postdoc.</p> <p>12 He's trying to put something into animal by</p> <p>13 injection and then he talk about, okay, let's --</p> <p>14 let's control that and try to verify this to a</p> <p>15 high quality so we can do.</p> <p>16 I honestly -- I don't know, right?</p> <p>17 So I'm trying very hard to, right, to tell you the</p> <p>18 truth of what I feel.</p> <p>19 Q. All right.</p> <p>20 A. It's hard.</p> <p>21 Q. Let's try this one last time.</p> <p>22 In forming your opinions, do you</p> <p>23 agree --</p> <p>24 A. Are you talking?</p>

<p style="text-align: right;">Page 398</p> <p>1 Q. I'm trying to. Do you hear me? I</p> <p>2 think your thing keeps freezing.</p> <p>3 A. Well, you talk -- talk aloud just</p> <p>4 now. I didn't hear anything you talk about.</p> <p>5 Q. You hear me now?</p> <p>6 A. Yes.</p> <p>7 Q. I'm really trying to ask a very what</p> <p>8 I think is a straightforward question.</p> <p>9 If I'm correct that when Min Li</p> <p>10 testified about this report, the report was</p> <p>11 talking about valsartan and that they had an</p> <p>12 "insufficient extent and depth of process research</p> <p>13 at the early stage, as well as insufficient study</p> <p>14 and understanding of potential genotoxic</p> <p>15 impurities," you would agree with me that's</p> <p>16 important to you to at least consider in forming</p> <p>17 your opinions about whether or not ZHP's risk</p> <p>18 assessment was adequate.</p> <p>19 You'd agree that it's at least</p> <p>20 something you have to take into account, right?</p> <p>21 A. I disagree. As I said, there's two</p> <p>22 stage of development. If there for those babies,</p> <p>23 early stage, very early stage, you have very</p> <p>24 different risk assessment toolbox that require.</p>	<p style="text-align: right;">Page 400</p> <p>1 THE VIDEOGRAPHER: Time right</p> <p>2 now is 6:41 p.m. We're back on the</p> <p>3 record.</p> <p>4 EXAMINATION</p> <p>5 BY MR. BERNARDO:</p> <p>6 Q. Dr. Xue, I'd like to ask you just a</p> <p>7 couple of questions on behalf of ZHP, and I'd like</p> <p>8 you to turn to page 55 of your report.</p> <p>9 A. Yes, I'm on that page.</p> <p>10 Q. And I want to go back to the</p> <p>11 questions that Mr. Slater just asked you with</p> <p>12 respect to the testimony that you cite, which you</p> <p>13 have a Footnote 122.</p> <p>14 Do you see where I am?</p> <p>15 A. Yes, I do.</p> <p>16 Q. Okay. Have you had a chance to take</p> <p>17 a look at that over the break?</p> <p>18 A. I did.</p> <p>19 Q. Okay. Dr. Xue, if Mr. Slater is</p> <p>20 correct that there's an inadvertent error there or</p> <p>21 that there's an error there that that testimony</p> <p>22 does not relate to irbesartan but, rather, relates</p> <p>23 to valsartan, does that affect your opinion with</p> <p>24 respect to the July 17, 2017 memo -- sorry --</p>
<p style="text-align: right;">Page 399</p> <p>1 I'm not a regulatory scientist. The regulation</p> <p>2 must be different, right?</p> <p>3 So if a postdoc come to me say, this</p> <p>4 first step you design not working, then I might</p> <p>5 just say, okay, that's it. Let's try a different</p> <p>6 project or try a different thing.</p> <p>7 I won't -- I won't use, apply a</p> <p>8 totally same risk assessment requirement to -- to</p> <p>9 other project like they are late stage. They</p> <p>10 already be almost ready to get to animal. So I</p> <p>11 don't agree with that.</p> <p>12 MR. SLATER: All right. I'm</p> <p>13 going to reserve whatever time I have</p> <p>14 left and, Rich, I guess if you requestion</p> <p>15 and I need to follow up, you and I can</p> <p>16 talk about time. I'm not looking to</p> <p>17 argue with you. I think I've been pretty</p> <p>18 patient. We can figure it out.</p> <p>19 MR. BERNARDO: I think we can</p> <p>20 figure it out.</p> <p>21 MR. SLATER: Go off the video.</p> <p>22 THE VIDEOGRAPHER: Time right</p> <p>23 now is 6:23 p.m. We're off the record.</p> <p>24 (Recess.)</p>	<p style="text-align: right;">Page 401</p> <p>1 July -- yes -- 17, 2017 e-mail in your report?</p> <p>2 A. No, it doesn't.</p> <p>3 Q. Does it -- does it change any of</p> <p>4 your opinions in your report?</p> <p>5 A. It don't change any of my opinions.</p> <p>6 MR. BERNARDO: Okay. That's</p> <p>7 all I have.</p> <p>8 MR. SLATER: Well, in that</p> <p>9 case, dinnertime.</p> <p>10 MR. BERNARDO: All right.</p> <p>11 Thank you very much, Dr. Xue. I hope</p> <p>12 you're feeling better.</p> <p>13 Adam, enjoy your dinner.</p> <p>14 MR. SLATER: You, too. Go</p> <p>15 off.</p> <p>16 THE VIDEOGRAPHER: Time now is</p> <p>17 6:42 p.m. Off the record.</p> <p>18</p> <p>19</p> <p>20 (Deposition concluded at 6:42 p.m.)</p> <p>21</p> <p>22 * *</p> <p>23</p> <p>24</p>

<p style="text-align: right;">Page 402</p> <p style="text-align: center;">ERRATA SHEET</p> <p>1</p> <p>2</p> <p>3 Page No.____Line No.____Change to:_____</p> <p>4 _____</p> <p>5 Page No.____Line No.____Change to:_____</p> <p>6 _____</p> <p>7 Page No.____Line No.____Change to:_____</p> <p>8 _____</p> <p>9 Page No.____Line No.____Change to:_____</p> <p>10 _____</p> <p>11 Page No.____Line No.____Change to:_____</p> <p>12 _____</p> <p>13 Page No.____Line No.____Change to:_____</p> <p>14 _____</p> <p>15 Page No.____Line No.____Change to:_____</p> <p>16 _____</p> <p>17 Page No.____Line No.____Change to:_____</p> <p>18 _____</p> <p>19 Page No.____Line No.____Change to:_____</p> <p>20 _____</p> <p>21 Page No.____Line No.____Change to:_____</p> <p>22 _____</p> <p>23 Page No.____Line No.____Change to:_____</p> <p>24 _____</p> <p style="text-align: right;">Page 403</p> <p>1 DECLARATION UNDER PENALTY OF PERJURY</p> <p>2</p> <p>3</p> <p>4 I declare under penalty of</p> <p>5 perjury that I have read the entire transcript of</p> <p>6 my Deposition taken in the captioned matter</p> <p>7 or the same has been read to me, and</p> <p>8 the same is true and accurate, save and</p> <p>9 except for changes and/or corrections, if</p> <p>10 any, as indicated by me on the DEPOSITION</p> <p>11 ERRATA SHEET hereof, with the understanding</p> <p>12 that I offer these changes as if still under</p> <p>13 oath.</p> <p>14</p> <p>15 Signed on the _____ day of</p> <p>16 _____, 2023.</p> <p>17 _____</p> <p>18 _____</p> <p>19 FENGtian Xue, PHD</p> <p>20</p> <p>21</p> <p>22</p> <p>23</p> <p>24</p>	<p style="text-align: right;">Page 404</p> <p style="text-align: center;">CERTIFICATE OF REPORTER</p> <p>1</p> <p>2 DISTRICT OF COLUMBIA)</p> <p>3 I, DENISE DOBNER VICKERY, CRR/RMR and</p> <p>4 Notary Public, hereby certify the witness was by</p> <p>5 me first duly sworn to testify to the truth; that</p> <p>6 the said deposition was recorded stenographically</p> <p>7 by me and thereafter reduced to printing under my</p> <p>8 direction; and that said deposition is a true</p> <p>9 record of the testimony given by said witness.</p> <p>10 I certify the inspection, reading and</p> <p>11 signing of said deposition were NOT waived by</p> <p>12 counsel for the respective parties and by the</p> <p>13 witness; and that I am not a relative or employee</p> <p>14 of any of the parties, or a relative or employee</p> <p>15 of either counsel, and I am in no way interested</p> <p>16 directly or indirectly in this action.</p> <p>17</p> <p>18</p> <p>19</p> <p>20</p> <p>21 Denise Dobner Vickery, CRR/RMR</p> <p>22 Notary Public in and for the</p> <p>23 District of Columbia</p> <p>24 My Commission expires: February 28, 2023</p>
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